

HIT Standards Committee Final Transcript February 16, 2011

Presentation

Judy Sparrow – Office of the National Coordinator – Executive Director

Great. Thank you. Good afternoon, everybody, and welcome to the HIT Standards Committee. Again, this is a Federal Advisory Committee, so there will be opportunity at the end of the meeting for the public to make comment and there will be a transcript available on the ONC Website.

Just a reminder, too, for workgroup members to please identify yourselves when speaking. And we'll go around the room and introduce ourselves, starting with:

Jodi Daniel – ONC – Director Office of Policy & Research

Jodi Daniel, ONC.

Nancy Orvis – U.S. Department of Defense (Health Affairs) – Chief

Nancy Orvis, DOD.

Kamie Roberts – NIST – IT Lab Grant Program Manager

Kamie Roberts, National Institute of Standards and Technology.

John Derr – Golden Living LLC – Chief Technology Strategic Officer

John Derr, Golden Living.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences

Dixie Baker for Applications International.

Martin Harris – Cleveland Clinic – Chief Information Officer

Martin Harris, Cleveland Clinic.

Cris Ross – SureScripts – CIO

Cris Ross, SureScripts.

John Halamka – Harvard Medical School – Chief Information Officer

John Halamka, Harvard Medical School.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Jon Perlin, HCA, Adjunct Faculty Venerable.

Linda Fischetti – VHA – Chief Health Informatics Officer

Linda Fischetti, Department of Veterans Affairs.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst

Wes Rishel, Gartner.

Judy Murphy – Aurora Health Care – Vice President of Applications

Judy Murphy, Aurora Health Care.

Jim Walker – Geisinger Health Systems – Chief Health Information Officer

Jim Walker, Geisinger.

Anne Castro – BlueCross BlueShield South Carolina – Chief Design Architect

Anne Castro, BlueCross BlueShield of South Carolina.

Christopher Chute – Mayo Clinic – VC Data Gov. & Health IT Standards

Chris Chute, Mayo Clinic.

Janet Corrigan – National Quality Forum – President & CEO

Janet Corrigan, NQF.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

David McCallie, Cerner.

Judy Sparrow – Office of the National Coordinator – Executive Director

And on the telephone we have:

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

Here.

Karen Trudel – CMS – Deputy Director, Office E-Health Standards & Services

Present.

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics

I'm here.

Judy Sparrow – Office of the National Coordinator – Executive Director

Anyone else from the committee on the telephone?

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer

Stan Huff.

Judy Sparrow – Office of the National Coordinator – Executive Director

And Stan. Thank you. With that I'll turn it over to Dr. Perlin.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Well thank you, Judy, and welcome, everybody to today's meeting of the HIT Standards Committee. I appreciate everyone that's here in person, and particularly appreciate the continued attention of the members of the Standards Committee who have been here not only for today's PCAST hearing, but yesterday as well. Want to thank everybody for their participation and attention.

To those who may be joining I imagine those who are on are probably aware that the last day and a half has been really very, very active with the PCAST, President's Council Advisors and Science Technology Federal Advisory Committee, hosting a meeting that also included members of the Policy and Standards Committee to discuss the PCAST report. So it's been a very full and very robust day and a half. I think those very rich discussions really help to inform our continuing work.

This is obviously a time of a great deal of activity, both within the form of the Federal Advisory Committee, as well as really for all participants outside. I know that those who are engaged in the activities of meaningful use know that today is not just a meeting of the Standards Committee, but I believe it's 135 days until July 1st of this year, not that I'm counting. So it is a busy time, and I think the discussions are so rich because there's so much opportunity to meet the goals, the aspirations for the use of health IT to really improve the performance of healthcare for all, including especially the patients, the center, and it's a very busy time for those engaged in all areas. I want to thank everyone for their continuing attention.

Towards that end, Dr. Blumenthal and his team have been really a constant part of the presence and discussions for the last day and a half, so we're going to move forward into the body of the agenda. We

have the benefit of their leadership and guidance and discussion and input over those last day and a half of meetings, and today we have a very important agenda.

I want to thank Dixie Baker and Walt Suarez as they're continuing to work in Certificates Management. We will also be discussing the Quality Measures. I mentioned the rubber hitting the road in terms of many entities really accelerating in their activities towards realizing ..., and as implementation occurs it really tests the premises of how sustaining such measures where it counts, how things are digitally represented, how they're coded specifically, and have robust discussion in that regard as well. I know that we'll have a good conversation about the direct project, indeed a great discussion earlier about all aspects of an exchange and direct in terms of meeting the aspirations of the President Council's report. And finally, some very robust conversation, we hope, about how the important work of our committee intersects with the Standards and Interoperability Framework. I think it's a conversation in which we really sort of reaffirm our connectivity, but also identify our different roles.

With that I want to turn to my partner, John Halamka, to provide further introduction to a couple of the topics, if you care to do so.

John Halamka – Harvard Medical School – Chief Information Officer

Sure. Great. So if we look at the ecosystem that we have today where we have the Policy Committee, the Standards Committee, the S&I Framework, and we want to ask ourselves the question how do all those pieces and parts intersect and what is the role of this committee, how do we take the rich experience of everyone in this room and ensure that as the S&I Framework is used as a process to harmonize standards and produce implementations guides that we are advising it to its greatest extent. And so I think as we go through the discussion today I want to make sure and raise all the concerns that any of you have about the S&I Framework, what it is and what it isn't, how we articulate with it. And as we get a charge from the Policy Committee, and whether that is Certificate Management or Provider Directories or other unique clinical content, how is it that we can assure that this whole process of getting us from Policy to Standards to S&I Framework to work product is orchestrated.

Now I think one of our challenges, and you've mentioned dates, if we recognize that an NPRM is going to be coming out by the end of the year for certification and standards for Meaningful Use stage two it's going to be important that we know what we have to do and when we have to do it to best contribute to that effort. And, of course, I would just guess, because I don't know precisely, but say next month the Policy Committee finalizes its recommendations on what will be in stage two we then ask ourselves the question how do we organize between April and October, let's say that's the frame, to ensure that we have looked at what is necessary, what are the gaps, and then offered our advices to the characteristics of the standards and implementation guides that are necessary and have those appropriately baked through that S&I Framework in time for the NPRM to reflect whatever work is done.

So this is going to be a challenging time; our time frames are highly compressed. So as long as coming out today we agree how we will all work together with the S&I Framework, then we hear what the timeline will be, which will hopefully be soon, then we can organize ourselves to get that work done.

So, as you said, we'll have that discussion. I look forward to the Certificate updates. Quality measures we have had, I think in Meaningful Use stage two and three are going to be enhanced in additional quality measures, and we should, of course, organize ourselves to have our Quality Workgroup reinvigorated to participate in all those quality measure activities. And on the direct side and on the S&I Framework we'll hear updates from Mariann and Doug. They are both in the West Wing currently, so what they said there are very few things that would ever trump a Standards Committee meeting, but the West Wing is on the bucket list so we can forgive them if they're slightly delayed. We may find that our S&I Framework discussion may begin, given the agenda, as they are on their way here, and that's okay.

So with that turn it back to you.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Well thank you, John. What they didn't tell you was that they're in the West Wing of this building.

John Halamka – Harvard Medical School – Chief Information Officer

Not true. Not true.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Want to recognize, particularly for those who are listening online, that Cris Ross and Walter Suarez, and who else wasn't here; I saw one other person come in. Anybody else who wasn't recognized at the beginning? So Cris Ross and Walter Suarez have joined. Anybody else who has joined on line? Okay.

Well with that our first order of official business is review of the agenda, and open at this time any comments, amendments. As you are contemplating any potential recommendations for change on those I want to thank the staff of the Office of the National Coordinator, as always, for very thoughtful representation of, indeed, very detailed and thoughtful discussions.

Hearing no objections, then, we'll assume consensus on the agenda and move into the body of the meeting. And with that, John, anything you want to introduce, or should we move right into the certificates management?

John Halamka – Harvard Medical School – Chief Information Officer

Well what I would just generally introduce the topic by saying the Policy Committee gave us a charge and the question, of course, when we receive any charge is should Dixie and her team be working on the bits and bytes of the designing precisely how a certificate standard should work and detailed implementation guidance should be given or should her committee define all the characteristics of how a certificate should function and what features it should have and then work in collaboration with the S&I Framework on the bits and bytes side of things, recognizing the S&I Framework provides a process by which hundreds of stakeholders can be gathered and many external projects can be aligned.

So I know, Dixie, you've been thinking about some of these issues.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences

Yes. I don't have a long report today, but the first thing I wanted to mention is that we do have a new member of our Privacy and Security Workgroup, Mike Davis from the Veterans Health Administration. He is a Senior Security Architect over there, and we're really pleased to have him join us.

As John mentioned, we've been given an assignment to work on two Standards areas, digital certificates to authenticate organizations and provider directories. And we've started on the digital certificate exploring the standards that are available for authenticating organizations and software, and we've had two meetings in that regard. Most recently we heard presentations both from Arien Malec about how digital certificates were used in the direct project and from Rich Kernan from Deloitte who is involved in the Nationwide Health Information Network Exchange specification, that's been known as NHEIN Connect. And so we talked and heard both of them explain how digital certificates are used in both of those environments to authenticate organizations.

We also heard from Mike Davis, who talked about how digital certificates are being used within the Veterans Health Administration to authenticate individuals. Now this was a level of detail, a level up from authenticating organizations, but the basic technology and the standards that are used are quite similar.

And so we heard these presentations, and then we learned what John was just talking about that moving forward there would be a complimentary type relationship between the S&I Framework and the HIT Standards Committee and that our role is likely to be changing slightly into more of one of providing requirements for standards and criteria for standards rather than really going out there and specifying, as John mentioned, the bits and bytes in the fields of X509 certificate.

So I know that we're going to be talking about that later, so I will just conclude at that point and let you know we'll continue to be exploring what are the requirements for standards in these areas in this new role.

John Halamka – Harvard Medical School – Chief Information Officer

Now, Dixie, I know that you have also been charged with Walter for working on some of the provider directory aspects. Do you or Walter have any comments about that ...?

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences

No, we haven't started ... the effort at this time.

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO

And obviously—

Jonathan Perlin – Hospital Corporation of America – CMO & President

Please go ahead.

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO

No, I was just going to add in addition to provider directories that we're looking at two aspects of it, the NCT level provider directory, which their recommendations came back already from the Policy Committee and that's what the initial focus would, and then where in the Policy Committee I work with we're finishing out the recommendations on the individual level provider directory. So the two are probably going to come back to the Standards Committee in some near term fashion, so it will be nice because the two can be wrapped around and the single set of discussions can be had about both of them.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences

We're fortunate to have a co-chair on this Policy Committee's Workgroup that's working on provider directories so that we can stay in lock step with what's coming out of that committee.

John Halamka – Harvard Medical School – Chief Information Officer

So here's a process question for you, and I realize you haven't met so this is going to be kind of an unfair question, but if I look at the world of provider directories there's some work done by HIE and there was a HITSP activity to look at provider directories. There are state level activities and regional level activities, and Massachusetts happens to have an entity and an individual level provider directory and some standards that are invented around those. There has been work by private companies, so SureScripts, I have to imagine, as part of its interoperability activities has a set of provider directory approaches. Some as restful, some are SOP based, some are LDAP based, some are more concerned with the authentication of in the individual rather than simply finding their address or routing information. So as you guys think about this interesting problem are you thinking of doing a survey of what is already out there, and then based on that survey making recommendations about characteristics? Will that be done in the context of an S&I Framework activity? I mean, again, may be a little early to ask that question.

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO

All of the above. No, I can offer a couple of thoughts. Clearly this has been identified as one of the various priorities for the S&I Framework, so I expect that this new iterative relationship between the Standards Committee and the S&I Framework will include this provider directory topic. And again, under that new relationship my expectation is that the group will provide the same kind of guidance and sort of the evaluation criteria and conceptual elements for the S&I Framework to go and do the kind of deep dive analysis on what are the actual approaches that exist today, what are the standards that exist today, and then come back to us with recommendations on which ones to go forward. So that would be my perspective on those.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences

Yes, that's my understanding of what you're going to present a little later in our meeting.

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO

Okay. So back to ... Okay. Good.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

John, I'd like to put my card up.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Oh please, Carol, go ahead.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

Well I was just going to also mention in addition to those two workgroups, as Dixie knows since we're both on the Privacy and Security Tiger team, there is also a discussion there about provider authentication, and I think all of these things are related and probably best kept in close coordination.

Jonathan Perlin – Hospital Corporation of America – CMO & President

So as we get these charges from the Policy Committee we are careful to try to align these things. So it just so happens that, Dixie and Walter, you have been given the lion's share of all of these initial requests, so provider directory, certificate management, authentication all are quite related.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences

Yes. And at this point they're all at the organization level as well.

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO

And certainly we're very pleased to learn more and define better this new relationship with the S&I Framework, because I think that is where the deep dive detail work that certainly a workgroup with 15 members cannot really achieve at this kind of specificity, so we're very pleased to be learning and better defining that relationship.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Okay. Well again our various workgroups, Privacy and Security will be working on certificates, provider directories, and from the Policy Committee over the course of the next month, as we see with stage two, will require there may be additional assignments, and we'll be mindful of your resource and timing and try to balance the work across our multiple workgroups.

Any other closing comments from you guys? Questions that folks have on certification management or provider directories thus far? See I figure we've tired everybody out after two solid days in this room, but at least you're all sitting now on the same tier.

Well then, Judy, with that I see that Quality Measures is next on our agenda, and is Thomas—

Judy Sparrow – Office of the National Coordinator – Executive Director

Tom is here. Yes.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Okay.

So as I mentioned, as we go forward with stage two and three there are going to be increasing numbers of quality measures, both ambulatory and hospital based, and ensuring those quality measures are relevant, are EHR derived, are computable requires the assistance of all of you. And certainly, Thomas, we'd like to hear your thoughts, your concerns, and your plans.

Tom Tsang – ONC – Medical Director

Great. Thank you. Good afternoon, everyone, my name is Tom Tsang; I am the Medical Director of Meaningful Use and Quality in ONC. It gives me great pleasure to really update the entire group of some of the work that the Clinical Quality Measure Workgroup has been doing from the HIT Policy Committee, and I hope some of the information that I give you today would help you decide some of the strategies and recommendations that we hope to get from this group as well on some of the future work in terms of vocabulary sets and standards.

So a little bit of level setting in terms of background, right now in stage one Meaningful Use we have the requirement of reporting three core and three additional CQMs, what we call Clinical Quality Measures, for eligible providers and 15 CQMs for hospitals. And the level of reporting right now requires aggregate level data, and that translates to numerator, denominator, and exclusions through attestation for 90 days for stage one the first year. In terms of what's available for providers to record there are 44 ambulatory care measures that have been taken from the PQRI subset from CMS, and what we've done was basically translated these claims based, administrative based data measures and "retooled" them with electronic specifications. We've asked NQF to actually help in terms of being the contractor for the retooling process.

Now retrospectively learning from that process we know that that is not the best process in place. A lot of these measures cannot be simply translated and mapped out into the structure of data fields inside in the HR, and so what we had planned about eight months ago was a new process to actually create the de novo E measures with the thought that we would leverage the information and the resources available in the EHR to produce new measures that would be really, truly meaningful and what we think are parsimonious.

The 44 ambulatory care measure the other thing is that they're very, very specialty focused and they're disease focused. What we wanted at ONC was actually prioritize a set of measure that could be cost cutting, that could be used in various setting of care, that could take advantage of the longitudinal nature of the HRs, and that's what we had set out to do. And so what we've done was really create a transparent and collaborative process involving a lot of key stakeholders, subject matter experts, and a community of measure stewards and measure developer community, and have them be involved with the FACA process. So created around six Tiger teams according to some of the domains that was part of the National Priorities Partnership.

This is kind of the workflow process for us. It's been quite an iterative process. So we set the domain according to the National Priorities Partnership domains as a foundation. We've identified measure gaps through actually this group called the Gretzke Group that Janet and the NQF folks had helped us put together, and from that Gretzke Group they outlined specific domains and certain criteria to be used for future measure development in the EHR environment.

And then we came up with a set of domains; we put it out for public comment around December. We've received well over 1,100 comments, and I'll show you the slide. We basically brought down the 1,100 comments to roughly about 490, and right now they're at the point where hopefully we can come up with a super set of measure/measure concepts, roughly about 30 to 40 measures where we say out of the 1,100 comments and measure suggestions these are the things that we really, really want to focus on for stage two and stage three. Some of them are at different levels of development where we could just basically retool them, others, probably 80% of them, need to be developed over the next two years.

And so ONC is trying to secure funding for the development process, and so that's where I think the linkage needs to be made between the Standards Committee and the Policy Committee in that the Policy Committee Quality Workgroup has come up with a series of suggestions for actually the measures and measure concepts, and now I think the Standards Committee we're asking you guys to actually give us guidance on the evolution of the data and the structured data for this, and I can talk a little bit more.

And so the Quality Measure Workgroup these are the list of participants. We had David Blumenthal and David Lanske Chairing and Co-Chairing, and you can tell from the list that we had a very, very diverse set of subject matter experts. We also had Federal Ex Officio members from several of the agencies that would probably use these measures and have some suggestions, because at the same time we're trying to juggle many, many balls at the same time. We're trying to harmonize a lot of these measures so that it doesn't impact and also reduces the amount of reporting requirements for the providers and for the hospitals so that some of these measures that could be developed could also be used for other programs, such as RHQDAPU, future PKRS rules for 2012, and potentially for ACOs and patient-centered medical homes, along with meeting the needs for SAMHSA and meeting the needs for HRSA.

I'm going to skip over that and go over it a little bit later. These are the five measured priority domains that we came up with. Patients and family engagement, and the three or four sub domains that we looked at were self-management activation, public health outcomes, honoring patient preferences, and shared decision support, and really thinking about innovative measures where we can actually import some of the data from patient self-reported experiences and functional status measures, for example. Clinical appropriateness/efficiencies another set of domain that was big on everyone's mind.

And then we came up with about four sub domains, the appropriateness and efficient use of facilities, such as a readmissions measure. Right now the readmissions measure actually uses claims based data; we're trying to figure out how we could digitize that measure. The appropriate and efficient use of diagnostic tests; there is this whole slew of measures that assesses the efficiency of using CAT scans, the appropriateness of CAT scans, and redundancy of multiple diagnostic tests.

The next big domain is care coordination; we'd like to leverage the capacity and the functional abilities of the EHR trajectory document that there's care coordination going on. I think where delivery system reform is going we all want to show that there is enhanced care coordination going on, especially in stage two and stage three Meaningful Use. The fourth domain is patient safety; we want to look at certainly areas of patient safety, medication safety, adverse drug events, health associated events that could be automated and digitized. And then, lastly, population and public health; we wanted to look at certain things that could actually take advantage of the longitudinal nature of measures across the continuum of care using an EHR.

This slide is about the request for comments. So, as I said, we received a number of comments from public stakeholders. We put it out in December, and we put it out for comment for about three weeks and we received comments from 134 organizations. These are some of the organizations that had recommended measure concepts and specific measures according to the domains and sub domains, so it's an extremely diverse and heterogeneous mix of non-profits, academics, measure stewards.

And these are some of the criteria that we used to actually think about the domains and measures: state of readiness, whether it's HIP sensitive or not, whether it's actually cross cutting in nature, parsimonious, whether it can reduce burden for a community, whether it can support patient health risk assessment, and then whether it can support longitudinal measurement.

So out of the 1,100 recommended measures we found that 491 of them are unique, and of that 79 of them actually overlap with 113 of the retooled measures. If you remember from the original MPRM for stage one there were roughly about 110 or so measures that were in the MPRM, and of that 110 44 have been used for stage one and there was a balance of about 68 or 69 measures left, and so the 113 retooled measures are retooling the 69.

And I'm just going to give you some use cases for certain domains. So what we've been discussing with the Tiger teams over the last couple of weeks is really honing in on what are the exact measures that we're thinking about or measured concepts or examples. So for patient and family engagement, for the most promising measures, we're actually thinking about incorporating patient experiences of care with providers, measurement of functional status and health risk, patient activation and self-management skills. And there are some certain methodologic issues in terms of how we do that, and I think these are some of the things that we need help on from guidance and asking you guys to comment and make some recommendations on certain methodologic issues that we need to work on over the next year or so.

Same thing with clinical appropriateness and efficiency; when we're talking about Lipper control using a Framingham risk score there is going to be some computational algorithm that's going to be laid over the EHR; how can we do complex computational algorithms on a measure when we're looking at, for example, the readmission measure or we're looking at over use and under use of medications, how can we use other data sources, such as PBMs and also from claims data, how can we incorporate other sources of data. And I think that's another thing that we would need expertise from the Standards Committee to look into.

So the next steps over the next few weeks we're going to get a final set of about 30 to 40 measure suggestions from the HIT Policy Committee Quality Workgroup. From there we're going to bring it back to you guys and all of you can actually help us think about what to do in terms of standards and vocabulary sets.

This is a slide that I stole shamelessly from the NQF about QDS, and this is something that's been funded by HHS over the last few years, it actually started with HITSP and it was initially funded by HRQ, that looked at an information model that can serve as a foundation of data elements that's cross walked to a certain set of vocabulary sets that can actually standardize the way we think about measures in terms of measure development and also interoperability of measures.

And so some issues that we need to think about moving forward are we'd like the HIT Standards Committee to think about recommendations and feedback on the data elements for future E measures. In using the QDS model developed by NQF and funded by HHS how can we easily use that model to move forward to think about other things coming down the pipe in terms of measure work from either the community or from HHS. We need guidance on the vocabulary sets for E measures and we need some guidance on methodologic issues related to these CQNs, especially things like patient self reported measures and delta measures that are taking advantage of the longitudinal nature of measures.

Questions from the group?

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

I'd like to put my card up. It's Carol.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Sure, Carol. I'd just like to start. So recently Beth Israel Deaconess as an organization went through the certification process as part of the meaningful use preparations that we're doing, and of course that required that we go through all the hospital based quality measures and demonstrate their calculation of the PQRI XML necessary to report them to CMS by 2012. Certainly we have great respect for the quality measurement work that's been done; it's been an extraordinary effort. But as I mentioned to Janet, the burden of the exclusionary criteria, which absolutely understands the base validity standpoint that clinical experts will want absolutely accurate measures, I will just tell you I've just pulled up some of our computations here. So for stroke II, this particular measure ensuring that people who have stroke are receiving appropriate antithrombotic therapy, exclude all patients who were discharged or transferred to a Federal health facility. Now I'm sure there was a good reason to put that as an exclusionary criteria. Of the last thousand patients that I have had with stroke one has been transferred to a Federal health criteria, and so it took a programmer day to try to figure out who in our cohort would have been transferred post discharge for which the computation of the quality measure has basically no difference.

Of course I may be completely unusual and I may be complaining out of school, but I would guess that we are imposing on this country a vast amount of overhead in the data capture, the programming required for the algorithms and reporting to create exclusionary criteria that may have a deminuous mathematical effect. Although they may enhance the face validity, I don't question that, we have to ask a bit about the cost benefit. So it is simply my plea to all of you, and to Tom, that as we go forward and look at E measures that we ask ourselves what is the cost of every exclusionary criteria that you add to an E measure.

John Halamka – Harvard Medical School – Chief Information Officer

... comment on that quickly?

Jonathan Perlin – Hospital Corporation of America – CMO & President

Sure.

John Halamka – Harvard Medical School – Chief Information Officer

Maybe it should be made explicit, I mean the point of exclusions is to protect reporting entities from unfairness. And maybe we could just make it explicit that if an entity looks at an exclusion and says that's

going to cost us more to collect than it could possibly be worth to us we'll take the hit on our score, so be it. I don't think anyone's intention was ever to put a burden; it is to protect people from appropriate care so you don't have doctors trying to strong arm patients into things that patients don't want, for instance, so you get good numbers.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Yes. And Janet, any comments that you would make? I mean I realize this is a juggling act; it's an impossible task to both want to create an accurate measure with face validity and reduce burden to the ...

John Halamka – Harvard Medical School – Chief Information Officer

It's to protect the reporters; it isn't for some abstract academic idea about face validity. It's just because it would be unfair if a patient says I understand, I don't want that, it would be unfair to count that against the reporting entity.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Sure.

Janet Corrigan – National Quality Forum – President & CEO

Yes. I mean I think you also have to realize the measures were not created with the intent of them being used with Electronic Health Records. These are measures that are created by predominantly specialty societies, and they were intended to be collected using special data collection instruments or through paper records. So you're taking tools that were created for quite a different environment than the one that they've been moved into.

Having said that, there is a school of thought out there that a measure must take into account everything that the user, and in this case the clinician that's going to use it on the front line, thinks is important to take into account. So there is a school of thought that some have about face validity being particularly important and that face validity requires that you take into account many factors that might influence a measure. We have this debate frequently in our expert panels that review measures and we hear a lot from various groups, predominantly those that represent providers and clinicians, that it's important to have a long list of exclusions. So I think this is going to be something that one has to work through for some time.

Having said that, right now in the measurement world we have two kinds of measures that are out there right now. We have those that were developed to run off of the paper records and take everything into account that one thinks is potentially necessary. We have another set of measures that run off of administrative data, and those measures take very little into account in terms of exclusions because they were structured to run off of claims data or things like laboratory results and pharmacy claims. And consequently we have the polar opposites here, the extreme ends is what we have measures for. I think what we're trying to do with EHR is to strike a middle ground. We want to take into account and exclude those things that really are important to the results of the measure, which would be a middle ground to where the quality world currently is at.

Jonathan Perlin – Hospital Corporation of America – CMO & President

And so you've both made excellent points. As I went through the certification process I was asked to actually list all inclusion and exclusion criteria used in the computation of each measure, and again I could be incorrect, but I had the sense that in order to achieve certification I actually had to adhere to the nature of the measure as it was written and that there wasn't a lot of discretion. So if that was incorrect certainly-- Jim.

Jim Walker – Geisinger Health Systems – Chief Health Information Officer

Well I think it would be worth discussing making it a policy that if an organization doesn't want to mess with an exclusion criteria and is willing to take the hit on their score that should be allowable. We still ought to try to get to the middle ground that's reasonable, but also then nobody is forced into something that was intended to protect them that they think is onerous.

Jonathan Perlin – Hospital Corporation of America – CMO & President

And also as these E measures are authored I really like the middle ground idea; that one looks at the burden not only of software and programming and all the rest, but workflow, because there are certain aspects of workflow that now need to be changed if you are going to capture the detail that is required or implied by the measure. I talked to several vendors about this and they said oh we didn't actually have that function in our software, but because of the nature of the measure we actually had to create a nursing function that allows them at discharge to do a certain act so that we can hit one of the exclusionary criteria.

And then one other side quality effect of some of the quality measures is although Meaningful Use stage one didn't necessarily include certain functional criteria for doctors or nurses the quality measures actually implied a set of functions that went beyond the intent of stage one in order to calculate the inclusion or exclusionary criteria accurately.

John Halamka – Harvard Medical School – Chief Information Officer

Dr. Tsang wants to weigh back in.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Yes, please.

Tom Tsang – ONC – Medical Director

Jon, I think you pointed out a lot of good observations, and I think moving forward one of the processes that ONC intends is really to test and validate some of these measures that are newly developed. So I think through that testing and feedback process we'll find out some of the burdens and hardships about these CQNs that's going to be developed specifically for EHRs.

And the other thing is that what we really need is standards that reflect some of these exclusions. We don't have structured data fields or structured data elements for like patient refused or patient is allergic, I guess that's a bad example, a patient's allergies for refusal for a flu vaccine, but if it's a patient refusal I think that's something that we could come up with in terms of standards to collect.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Let me just make one last comment in that regard. There is a SNOMED NCT code for comfort care measures only, it's just I don't know of any EHR that has actually implemented it. So again, it gets back to this whole question of what do you capture, who captures it, are you forced as part of a certification process to capture it.

Now did you have a comment from a CMS perspective?

Janet Corrigan – National Quality Forum – President & CEO

No. From a DOD perspective new question. I have a different question.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Okay. Your ... on this thread, David?

David McCallie – Cerner Corporation – Vice President of Medical Informatics

This is David McCallie. I just would echo Jon's point that this is quite burdensome to the software process, and as you contemplate introducing these new measures that the lead time necessary to deal with the impact on the software is profound for all sorts of reasons, not the least of which, as Jon pointed out, is the workflow. There just may be no place where the data is being currently captured or no one whose role it is to capture that, so it's workflow in the software and workflow in the institution. So when I look at the discussion board of our clients who are wrestling with achieving stage one of meaningful use it is overwhelmingly dominated by questions around the quality measures; everything else is trivial compared to the quality measures. So if you drop a whole bunch of new ones that are complicated at the last minute it won't work; the vendors won't be able to get there and our clients won't either. So that's my comment on that thread.

I have a second question about the longitudinal measures. You refer to a longitudinal EHR and there aren't very many of those; most EHRs have vertical slices of the data and a longitudinal records requires some form of HIE, and from our discussion this morning the status of HIE for stage two seems quite confused and uncertain. I wouldn't go way out on a limb suggesting that a lot of longitudinal measures make sense in stage two if we haven't figured out what HIE is going to look like in stage two, much less implement it.

Tom Tsang – ONC – Medical Director

I think those are some of the methodologic inputs that we need to take into consideration when we actually go ahead and develop these measures, and that's very helpful. Thank you.

Jonathan Perlin – Hospital Corporation of America – CMO & President

And I'll come back to you, Janet, but Carol, did you have a comment in this thread?

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

Well, yes, and I guess it's not a comment so much as it's a clarifying question in terms of what the Standards Committee is being asked for. I guess I'm just a little confused by some of the presentation in the sense that my understanding is that the quality measures that are being reported are being reported as summary measures, numerators and denominators. Yet, some of the questions I heard in the presentation sounded like there was an intention to combine other or additional data sets and asking for detailed standards that might be collected. Is that in order to provide them to the vendors in order to program them or is that because there's a view that the detailed underlying data is being collected?

Tom Tsang – ONC – Medical Director

Carol, I'll take a very specific example. If we're looking at a clinical quality measure that's looking at diabetics between the ages of 18 to 85 whose HB1C is greater than 9, and that's the numerator and the denominator is all diabetics, I think now this concept has to be translated into very specific vocabulary sets, so how do you define diabetics? So currently right now we're defining diabetic using ICD9 and SNOMED codes. We're also defining diabetics as those that are taking very specific medications such as oral hypoglycemics and insulins.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

I understand that. I'm just asking, are the specifications you're asking for because you want to collect each field according to those specifications or are they being asked for because they need to be specified to the vendors in order to program them the EHR?

Tom Tsang – ONC – Medical Director

I think it's both. And what we like is to have the Standards Committee think about the evolution of this information model and the necessary data elements that's cross-logged to the necessary vocabulary sets.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

Sure. I guess my question, then, is more of a policy question that is basically has it been decided that CMS will be collecting detailed identified data on people?

John Halamka – Harvard Medical School – Chief Information Officer

Let me just ask it in a very specific way. This is data PQIXML is numerators and denominators. They're very aggregate queries. QRDA, as you evolve to different kinds of standards and data representations, might you have either the submission of patient identified or de-identified patient level numerator or denominator data?

Tom Tsang – ONC – Medical Director

So that policy has not been cited. I think right now as it stands, how we're using, what we're using to calculate the aggregate data is really just individual...we're using C32 and CCR files and that's what we're asking in terms of the certification process. At this point right now we're not collecting individual patient level data.

John Halamka – Harvard Medical School – Chief Information Officer

So I think the answer, Carol, to the question is, a policy of collecting patient individually identified data has not been made.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

Okay, thank you. That was the clarification I wanted to understand.

Janet Corrigan – National Quality Forum – President & CEO

I just really want to commend Tom and his group for trying to find their way through this very thorny set of issues. The one thing that I worry a little bit about, Tom, and I'm sure you're already thinking about it, is as you take these two measured concepts and contract out for measuring developers to develop E measures, de novo, I think it's going to be really important to connect to those developers, those measuring developers up with a testament of organizations that have EHR's running as well as those that think about this from that perspective, because the established measuring developers, they don't come from that world. They've been developing measures for a decade or two thinking from the perspective of the paper record and I don't think that even though you say, okay, now develop your measures de novo for EHR that they're going to know necessarily how to do that or anticipate. Some of it, obviously, they can. And plus, it's just such a new field developing these measures de novo, we have found that there were some leading systems that had done some of this internally, but we didn't see a lot of really well developed measures come forward in the process. We saw measure concepts and there's a big difference between measured concepts and well developed measure. So it's going to be critical to have a lot of back and forth as these measures begin to take shape and we think about numerators and denominators and make some of those decisions, to be able to test them, run them in a real environment.

But in addition to that, to probably also provide some pretty clear direction to the measures with all of this up front. What you want in terms of exclusions? What is the threshold, how do you want them to make those kinds of decisions at the very get go? You'll also get very different measures if you have multiple measure developers because they follow different conventions. That's why it's been so critical to hook them up with the quality data model and sort of the E measure authoring tool and things that are under development to try to structure some of the ways that they do things and in the specification.

Tom Tsang – ONC – Medical Director

We agree with you, Janet. I think having a test consortium of advanced users who can give us direct input and work with the measured developers will be critical in this process.

Jonathan Perlin – Hospital Corporation of America – CMO & President

And piloting these kinds of measures, because I think you stated it very well. I asked CMS, in the past there has been a skipped method where one looks at a sampling of charts through manual abstraction and we've moved from that to 100% numerators and denominators and E measures, but yet the exclusionary criteria that were in the former world paper-based are still included in the E measures to some extent. So wait a minute, do you want me to do sampling and figure out these funky exclusions or do you want me to do 100%, but somehow miss the exclusions and do I have that option? So, Jim, your comment is very appreciated, which is it could be up to the individual to decide the burden versus the cost of skipping a certain type of criteria. Especially if the workflow or the software engineering required were overly pertinent.

Sorry....Karen Trudel and I said CMS, but of course it's DOD.

Karen Trudel – CMS – Deputy Director, Office E-Health Standards & Services

I wanted to ask Dr. Tsang, back a couple of slides where you're asking, where the most promising measures are being discussed, and I was thinking of what those implications might be for the HIT Standards Committee. Particularly, you've got lipid control, in the area of radiology you've got diagnostic imaging procedures for redundancy, cumulative exposure and appropriateness. One of the things my organization has been wrestling for a couple of years on how to properly document certain things about radiology procedures and I did go back and saw that you had the appropriate professional organization,

American College of Radiology is in there and maybe Radiology North America, some of those areas will be difficult, I believe, because I don't believe there are data elements yet or reference terminologies developed for cumulative dosimetry. I'm pretty sure most vendors today, other than maybe an OPAC system, may not be able to accumulate the actual exposures on a patient.

Now for my population, which is in DoD and Wounded Warriors where someone may have 20 to 30 surgeries from point of injury to an amputated limb, that is a critical question for us in the coming years. What is that? So I think there's a challenge. And I guess given that we have six months to come up with stage II criteria, I'm kind of thinking what are you folks in that area of promising measures of radiology going to, we may need to have some pretty tightly coupled works with the vocabulary and the terminology subsets of this group in order to meet anything that you might want to do on radiology.

Tom Tsang – ONC – Medical Director

That's exactly the challenge that I'm posing this group is that over the next perhaps two weeks, two to three weeks, we will get a final subset of measured suggestions and measured concepts. As far as I understand it, the quality workgroup in this Standards Committee has been in hibernation for quite a while.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Hiatus.

Tom Tsang – ONC – Medical Director

Hiatus. Excuse me. And so what I'm posing to the group is, take a look at the list that's going to be recommended by the quality workgroup of the Policy Committee, take a look at these measures and measured concepts and see if it really makes sense. Is it feasible, is it reasonable? Do you think we have the vocabulary sets for it? Then look through the lens of the QDS model and give feedback to NQF and say does that make sense? Does it have the necessary data elements? Do we have the technology? Do we have the standards? Do we have the vocabulary sets to actually do these measures?

And out of the 40 or so suggestions, you may say, hey, you're going to have to cut out these 20 already, because we don't think this is going to be reasonable or it may be too aspirational.

Karen Trudel – CMS – Deputy Director, Office E-Health Standards & Services

But the really key point that I like about you actually putting these on here for us as a committee is – and I'm sorry that Chris was not here yet – is that this is exactly the kinds of issues that I think the Standards & Interoperability framework has to address. We need to bring up, early and quickly, that there is no terminology or reference for radiology orders or lab orders, or certain attributes that we want to collect and we need to get working on this stuff or the S&I framework needs to help do this, because those have to be developed 12 to 18 months ahead of when you need to be able to implement them so you can give them to implementers. So it could be feasible that we'd actually be looking for something like that for stage III criteria, but the work needs to begin now and next year to get things in place to be able to have that even as a candidate for stage III.

Tom Tsang – ONC – Medical Director

I can tell you that the bulk of the suggestions are for stage III as opposed to stage II, just because of what you had commented on. And there's the lag time and the lead time we need.

Karen Trudel – CMS – Deputy Director, Office E-Health Standards & Services

But I think it's absolutely the right way to go, but in the long-term engagement with the S&I framework I think this is a point of discussion that we need to bring up. It's not only that the S&I framework as it kicks off this year needs to work on issues that will help stage I implementation, but it needs to be putting in place how can we use that framework to get some missing pieces for exchange specifications in place so that we can even begin to use them for II and III. So I think this list will be very useful to help us set priorities in other kinds of work that we will need to address for the third stage.

Jonathan Perlin – Hospital Corporation of America – CMO & President

...requested that we reinvigorate the quality workgroup. I purely have some process questions, which is, now John, I believe you've chaired the quality workgroup in the past. Is there any issue of NQS as the contractor working on some of this for ONC with you also being the chair or do we have to name an independent chair? Maybe the legal folks can weigh in how this should be reconstituted.

Judy Murphy – Aurora Health Care – Vice President of Applications

I'd prefer that you appoint another chair, frankly, because I just feel a little bit conflicted in the process given the amount of work that we're doing that's flowing into this and it gets problematic. And I also think that it's important, before this rolled straight into the quality workgroup, I think it really is important that the Standards Committee overall understand what the quality data model is and whether or not they're comfortable with that model, how that model should evolve. I don't think that many here have really had much involvement with it, so it does seem that the Standards Committee should, first of all, feel very comfortable with the model that's being proposed and put before you. And then, as I understand it, the task is two-fold, to provide direction and guidance to NQS committees that work on evolving the model, so you need to provide input into the NQS process for this model as it is maintained and goes forward and adapted for additional measures under our contract with ONC, but then second, I think what you're thinking, Tom, is a preliminary sort of assessment of the measured concept and whether it's going to be feasible to think about those concepts for 2013 or 2015 and provide immediate feedback before you put your contacts in the field probably and get these measures developed.

Jonathan Perlin – Hospital Corporation of America – CMO & President

That's Judy Sparrow from a purely process standpoint, to seek a new chair for that workgroup. Should we seek cell phone nomination volunteers to you? I do look at the Quality Measures Workgroup and doing the diagram of those who are in your workgroup and sitting around this table, I see James Walker at Geisinger is shared in common. I'm just asking where there might be synergies. You're on tiger teams here and there and here. So is there a process for nomination?

Judy Murphy – Aurora Health Care – Vice President of Applications

Why don't we see if anybody wants to send me an email to express any kind of interest and then I can go and see, we'll have to sort of take all of that under advisement. Is that a good process?

Jonathan Perlin – Hospital Corporation of America – CMO & President

There is fame and fortune to be had.

Judy Murphy – Aurora Health Care – Vice President of Applications

Yes, mostly fame.

W

Then we can discuss that with you as the chair of this committee and make sure that we have that....

Jonathan Perlin – Hospital Corporation of America – CMO & President

Very good. Certainly, any interests that you folks feel, please give in touch with Judy.

John Derr.

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer

This is Stan Huff. I'd like to raise my card.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Very good. Thanks.

John Derr – Golden Living LLC – Chief Technology Strategic Officer

This is John. You all know I represent long-term, post acute care, which are the ill tax and the SNIFS and the hospice and home care. I just need advice I think from the group and from you, Dr. Tsang. I made a statement a number of months ago that when we were in stage II, should we assume that we're going to include all these other providers, especially in the quality measurements. We've already as a group

decided that we aren't going to give any incentives, and I've been working with Janet and other people and also Dr. Tsang and that about working on the quality measures to harmonize them across these other providers and vendors. And the providers and vendors are asking me now what role they could play. And I thought in stage II, even though we might not get the incentives and they are...because we're not in the legislation, that we would at least consider these other providers and their vendors in part of the stage II quality measurement exercise.

We also have CCHIT, a certification for home care and for skilled nursing facilities. And I just testified to the National Governors Association who are very interested in how we get interconnectivity with these other providers that we seem to omit in all the things we do. I know I commented on this process that you did and I don't see one organization on there that is representative of any long-term post acute care associations. We're trying very hard to harmonize with the group even though we seem to be left out a lot, and I need advice on whether I should keep pursuing all my people – and this represents 20 some organizations – to do quality measurements and working with the SNIF group and also the home care to harmonize and sort of have a matrix that says here's what we have for hospitals and doctors and here's what we might have? So that when we start interconnectivity in the EHR, and especially when we look at longitudinal care, that we have these quality measures— The advice is, are we going to continue to leave these people out of the process or how do we include them into the process and what should I tell people? I got asked yesterday to answer three questions from the pharmacy, consultant pharmacists, "John, why aren't we included? Why are we doing this?" And I try to answer the question because I don't really know the answer to the question. So I have, as I've told you guys, we're not complaining about not getting incentives anymore, we just want to be players in the team and I need advice, from somebody, somewhere, to tell us what we should be doing besides sitting back and saying in rehospitalization and discharges and transition of care, we just won't do anything until CMS tells us what to do. And I think that would be a terrible mistake.

So advice is what I'm seeking, because even this morning in PCAST I did a word search the other day when I reread it for the second time and long-term care was mentioned once in that 98 pages that they had in PCAST.

Tom Tsang – ONC – Medical Director

Of course above my pay grade, but I would guess that in the world of accountable care organizations nirvana that it is absolutely key that we include every element in the care delivery process and measure care and cost. And, therefore, it would be very important to include your stakeholders. But there are others who are closer to this than I.

John Halamka – Harvard Medical School – Chief Information Officer

To Tom and responding to John, I think you're absolutely right, and particularly as we move into stage II and III we talked about care coordination, transitions of care, patient-focused care, all of that is silly if we don't have long-term post acute. So I endorse that in the strongest possible terms. I think we ought to make sure that the measures are designed so that they work for the whole health care team and serve to admit that team together for the patient's benefit and we just have to do it.

Tom Tsang – ONC – Medical Director

John, I think when we look at some of these measures and the measure prioritization process there's also a few other balls that we all need to juggle within HHS is to make sure that the needs of all standards of care are well represented in the measurement process, and one of them would be the long-term care process. And I think your input continues to be valued and would be critical, I think, as we think about measures, especially just in the areas that you talked about, care coordination and readmissions and transitions in care and even documenting the care coordination. I think as we go about developing these measures, it's critical that we get your input because it's going to be the bulk of what you guys do. So I hope we can enlist your help.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Great.

John Derr – Golden Living LLC – Chief Technology Strategic Officer

We want to do that. I just wish that every once in a while somebody would put something in the reports to show these people that we do care about them. I mean, all you have to do is to mention LT PAC or something like that. Otherwise, at one point I'll lose all the cooperation of these people and they'll stand back and do what they have done in the past and that's wait for CMS to tell them what to do, and I think that would be a terrible thing to do. Especially, David represents a vendor that has all aspects – home care, hospice care and hospital things – I don't know what to tell the guys that ask me even in his company about the quality measures and harmonizing.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Well very fair point. I think this is good advice to all of us.

John Derr – Golden Living LLC – Chief Technology Strategic Officer

Not complaining. Just asking for advice.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Well, Dixie and then after Dixie, Stan. We haven't forgotten you.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences

This is kind of related to what John had said. I know that ONC is very concerned, and in fact David has written in his letter before about the low adoption rate, EHR adoption rate for the underserved. And I recently became aware of the additional burden that these quality measures are placing on providers of care to the underserved, particularly those who are funded by multiple federal agencies. Two concerns. One is that the measures may not easily be applied to that population, that segment of our population, and also the additional reporting requirements over and above what they said...and HRSA, etc.

So, my question, number one, which also relates back to John's comment earlier is that in these criteria you have something called "presentable burden." Shouldn't presentable burden also include burden on software developers and providers? So secondly, is there any effort to look at reporting requirements of all of these federal agencies that are funding, like the federally qualified health centers, to make sure that these quality measures are inclusive of what they already have to report? And third, shouldn't the working group include somebody that represents that segment of our care population?

Tom Tsang – ONC – Medical Director

Those are great points, Dixie. If you look at the partners, the federal partners that's represented in the quality workgroup, you'll see representatives from HRSA from SAMSA, from CMS and ...Medicaid as well as Medicare. I think the harmonization process is extremely important to all of us in the HHS for enterprise. In fact, within the Affordable Care Act there's a provision that says the secretary has to come up with a strategy by 2012 for harmonization of PCURI and meaningful use. So to reduce the burden on providers and to the reporting requirements, there is ongoing activity right now to try and do that, to harmonize across the agency, across the department, and that's why the newly configured or as we talk about the quality workgroup for the Standards Committee, I would make a suggestion that we add some federal ex-officio members as well from those various agencies to actually comment.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences

We're providers from the escalated, people who actually provide care in the street.

Tom Tsang – ONC – Medical Director

That's a great observation and we are trying to get that. Thank you.

John Halamka – Harvard Medical School – Chief Information Officer

Two final comments and then a wrap up from Dr. Perlin. So Stan Huff.

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer

I just wanted to second the earlier suggestion that we actually review QDS and their approach to vocabulary sets and E measures. Everybody there maybe knows and I'm the only one who doesn't, but I

don't have any familiarity with that area. And so it would be very useful if information could be provided. Or even better, if we have, in some sessions we actually had some review and tutorial on what those things are and what the approach is.

Tom Tsang – ONC – Medical Director

Great.

M

Judy Murphy.

Judy Murphy – Aurora Health Care – Vice President of Applications

I would just like to comment on your slide seven that has the stage II priority measure concepts. I think it's an absolutely wonderful idea to have a framework, and I commend you on listing that out. I think one of the difficulties that we had with the stage I quality measures was that they just seemed isolated. VTE and stroke and ED throughput, why those? So the fact that we're organizing around a framework I think makes a lot of sense.

That being said, there's a relationship between some of the things on this proposed framework with actual meaningful use criteria. So, for example, interdisciplinary care planning, I believe it's called on the current meaningful use criteria for stage II, and you've got affective care planning listed here. So half of me is thinking that maybe the quality measures get married in a tighter way with the actual meaningful use criteria rather than being just this sort of separate criteria. So, in other words, the meaningful use criteria might say you have to have interdisciplinary care planning and then the quality measure to demonstrate that it is effective would be within your domain. That seems like it would be a really good way to pair things up.

That's my comment. One quick question. You were talking about 40 concepts that are probably going to be vetted in the next 30 days. Are those actually going to be out for review and possible comment again or is that going to be locked and loaded when those get published?

Tom Tsang – ONC – Medical Director

The quality workgroup is meeting actually Friday morning to endorse those vet. And then after that it will be presented to the HIT Policy Committee on I believe it's March 2nd and that will be put in the public domain for comment.

Judy Murphy – Aurora Health Care – Vice President of Applications

Thank you.

John Halamka – Harvard Medical School – Chief Information Officer

Great. Jon Perlin?

Jonathan Perlin – Hospital Corporation of America – CMO & President

I want to thank everybody for a very robust discussion. This is very ...and I'm going to reframe the way it was said on the basis of Judy Murphy's comments, which I think are sort of useful in terms of tagging the evolution to some of the challenges that were described. As John indicated, some of the measures which make sense in an absolute frame are difficult to put into implementation because of the rarity of certain exclusionary criteria.

When it comes to the point of parsimony, and to which you point here as ...across multiple providers, care settings and conditions, really has taken it back to our role as the Standards Committee is how do we help support a set of reusable elements that are also part of perhaps the measures set and perhaps independent from the specifics that would occur in any specific measure set. What do I mean by that? You give a terrific example, patient refusal. That came up in discussion a number of times. Things that can become a set of building blocks, a set of standards that are useful to have a discussion about the presence or absence of certain activities.

I'd also like to mention parsimony from another perspective as well. We're talking about measures in a number of different senses. I like the way in which both QDS and the slide seven that Judy indicated, think of the number of different aspects of care of the patient. But another frame that you alluded to was the difference really between measures which support the interactivity of different providers and the patient and the process of care that actually become more robust with ...information, and those measures which may or may not overlap that you also alluded to that are accountability measures as in reporting hospital quality data ...or the present HIQR, the hospital inpatient quality reporting program and hospital outpatient quality data reporting program. I know CMS said we're not supposed to pronounce those, but trust me, they're being pronounced. That almost in itself is comment that there is a lot that's out there. There's an issue of parsimony in terms of the accountability measures and transformation and the ability to drive care reinforce meaningful use process as well.

Finally, in the entire process that's not value neutral there are choices that are made. But something that I think is particularly useful in terms of thinking of the potential differences between accountability and informational measures is that the accountability measures are very specific in the sense that they are the interrogative of implied decision support. I think that becomes tremendously important in terms of decision support that that's something that we're building standards to support the implementation of as a succession of stages of meaningful use.

So wrapping this together, I would echo the sentiment of how we build reusable sets that also support the evolution that's implied in meaningful use in a way that really helps to build the structure for measurement before we reach, perhaps, for measures that, taking back to the role of this committee, neither the standards nor implementation capacity I think it's going to be a sequential amount, that sort of conversation, that really provides back to us guidance on how we can help sequence for the greatest effect, both in terms of the informational nature in supporting continuity of care and contiguous information among teams. But also, the interlinkages – I'm sorry Karen's not here—but the interlinkages with the other programs that have great traction to draw things forward. Thanks.

John Halamka – Harvard Medical School – Chief Information Officer

So next steps we reinvigorate the quality workgroup. We select a new chair and we do a QDS education session that starts in that group and, of course, would involve any other interested members. And it sounds like we also need to enhance the membership of the quality workgroup to include those constituents that you think will help inform the burden of calculating some of these quality measures.

Great. Thanks very much for a robust discussion.

Let us move on to the Clinical Operations Workgroup. Is Liz Johnson on the phone? Okay. So remember, there are three threads of work, actually two threads of work assigned and one probably to be assigned in the Clinical Operations Workgroup. It's medical devices and how it is we will do interfacing. Specifically, this is more about vocabulary standards than it is about transmission standards.

In general, as we have this S&I framework discussion and welcome back from the West Wing, I hope that was fruitful for you. Did you bring us any cufflinks or any other souvenirs? We received a recent transmission letter from the Policy Workgroup regarding patient matching, and that has not been worked. It's been assigned, but it requires doing code sets around the demographics to create the most robust patient matching among entities possible. This is more binding vocabulary at the source for our PCAST discussions of the last two days. And I would guess Jamie is now traveling and so we would want to have the discussion with him, but because it is about code sets and vocabularies around demographics, that would probably belong either in the clinical operations or in the vocabulary workgroup.

So with that, Liz, tell us about the medical device here.

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics

We will do that. Judy, did you load the slides that I sent you?

Judy Sparrow – Office of the National Coordinator – Executive Director

You'll have to say "next slide" though, please.

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics

Of course. As John indicated, Jamie is traveling and so we have, and please catch, very brief update to the Standards Committee on the work that the Clinical Operations group is doing related to medical device interoperability. Next slide, please.

So in essence, what the objective of the hearing is is to really look, as you can see, barrier enablers for device interoperability and we really do want to focus on the standards, whether they are in place or not. And it was interesting, I think that we are truly still in the formation of who would even participate in the panels that I'll show in the next slide, but as you begin to talk about connected medical devices, we talk about device vendors and software vendors and publishers of standards and the conversations have been very fruitful, but we're still trying to, as you'll see, we'll move to the next slide.

The panels in the first two are pretty self explanatory, so we want to hear from patients and consumers that are using connected medical devices to sort of set the foundation on what their experiences are and what issues they may have found and where it's working for them and whether they want additional kinds of functionality. Secondly, we want to hear from our hospital providers and physician providers in using those devices in the care of those patients. How is it being used? And again, where are they finding difficulties and so begin to think about integrating that information into their existing medical records.

Then we go into a set of four additional panels that will be looking at a whole host of parts and pieces of medical device interoperability. We really want to look at the interoperability itself and the integration and certainly looking at continuing on HL7 and others. And then we want to talk about data accuracy and integrity, the validation of data, metadata tagging and again, looking at those types of persons and the kind of people that can bring us information about that kind of moving forward. And we would be looking there at also not just from a manufacturing perspective or standards, but also from those who are actually involved in this kind of work.

We would then look into a panel of device security and data security. We think that this is going to be critical in terms of moving data around and what kind of standards are already in place and who do we need to turn back to and really looking at that. Talking particularly, for example, with healthcare security alliance and so on.

Then as if the day isn't full enough, we will move into universal data identifiers and how would those be used and how can we report from those and so on. So to say to you, and I know that Stan and Chris and Nancy and Walter all have participated in these conversations along with a number of other members, for example, from the FDA in trying to begin to formulate this panel and the kind of information we want to attain, the panel will actually be held on March 28th. It will be an all day hearing...Standards Committee in the March conference. So John and then of course other workgroup members who might want to ask or clarify. Like I said, we're pretty early, but Jamie wanted to at least begin to get the concepts in front of the Standards group.

John Halamka – Harvard Medical School – Chief Information Officer

Given that in the future of a...care organizations and various new payment schemas that the home care is going to become increasingly important, the notion of being able to interface devices in the home, THR's and PHR's is going to be critical. So this is very, very important work and I think it's going to be an important hearing. So let us go around. Nancy?

Nancy Orvis – U.S. Department of Defense (Health Affairs) – Chief

I think this is a perfect time to mention John Derr's previous conversation. This hearing on March 28th should definitely be broadcast to the long-term care, chronic care, home care community. Because, again, this is part of the reason this industry is coming forward, because they want to help create seamless interoperability of data to a patient EHR. So I'm glad to know, as you said that, I immediately thought of this hearing and I want to make sure, maybe we explicitly link that and call that out, that as we

send out questions or something like that, maybe the folks who testify may be able to particularly bring out benefits, the value stream or something in this area.

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics

That's a great idea. I made a note of that so we can get it back to the workgroup.

John Derr – Golden Living LLC – Chief Technology Strategic Officer

...proacted on that part. In fact, I just emailed the guy at National Home & Hospice Care the date is the 28th. And I'm on a committee and I've also talked to American Telemedicine Association, which in the ACO world is going to be very important to have them on a committee. I asked to be on that workgroup from Jamie and I also brought a guy with me who's a homecare expert. And I have everyone standing by.

John Halamka – Harvard Medical School – Chief Information Officer

Liz, make sure that you use the appropriate acronyms describing the various organizations that John Derr assists with. This way we'll show the love.

Nancy Orvis – U.S. Department of Defense (Health Affairs) – Chief

Just in general, also, Liz put these slides together for us and it was great. I think we're going to try and talk about both medical device product information as well as the data it transmits, because one of the key issues in an EHR that we haven't come up with yet is a patient care summary of medical devices necessary to maintain that person's health. I think in panel 6 with the universal device identifier it's important to note that things such as durable medical equipment as well as artificial limbs are all considered medical devices. As we saw with other natural disasters where folks lost everything and you need to get them back up in a maintenance mode, there's many things they need be, besides medications in order to maintain a status quo on their health, whether it's a walker, nebulizers or whatever. So I think it is important to realize, and I think the FDA is going to be part of our members on this, too. It's very important to know that, because I think we're also looking at how, what the manufactures think here and what they would end up having to put out as requests for industry input on are they willing to supply this kind of data. I think this should be a very good hearing.

John Halamka – Harvard Medical School – Chief Information Officer

Carol, on the phone?

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

Yes. I just wanted to offer, Liz, I know I missed the last workgroup meeting, but I just wanted to offer to try to help at least with some elements of the topics that you listed, particularly on the patient consumer one. I wanted to flag also that it's really interesting since it's part of the proposed stage II meaningful use to hear from consumers who have downloaded their medical record, like from the Veterans Administration, which I don't know if Linda's in the room, but I understand there's well over 100,000 that have done so now. And it would just be good to understand both the simple and the more complicated interactions that patients and consumers are having and the value that they derive from that.

The second thing I wanted to ask was in your comments about data tagging and metadata tagging, were you suggesting that there was an openness to look at other sectors?

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics

I think there's an openness to look at it, Carol. I think what we really were doing was tagging the data from the devices. Is that what your question is?

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

I thought you had referenced the PCAST report.

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics

No, I did not.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

Alright. Maybe after two days everything sounds like that. I thought maybe there would be an opportunity, because I think it would be really interesting to hear experience from other sectors in that regard when we...

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics

It's a great idea and I'll bring it back to the workgroup, but we hadn't gotten there yet. Kind of like yourself having spent the day with you guys yesterday, we've heard a lot about PCAST in the last couple days.

John Halamka – Harvard Medical School – Chief Information Officer

Chris Ross and Wes, you're up.

Christopher Ross – MinuteClinic – Chief Information Officer

Do you have a definition of device that you're using for this?

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics

We do not, but we have talked about the FDA definition. That's one of the things that we will provide to the Standards Committee prior to the panel. Because we went through that description and we did come up with some descriptors, but we did not land on a specific one, which I think will be necessary just to set the boundaries on the panel discussion.

Christopher Ross – MinuteClinic – Chief Information Officer

That's great. If you haven't completed that, I would make maybe a case to include devices for diagnostics as well as ungual care. And I don't mean all treatments for diagnostics. I'm not talking about x-Ray and MRI. I'm thinking about things that are perhaps more aligned towards home health. I'm thinking about Glucometers, I'm thinking about pulse oximetry, spirometry, other kinds of things that might be used for chronic care that are relevant to a lot of the measures we're otherwise looking at.

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics

Right. And we had talked about things of that nature, so you really have nailed sort of some parameters that we've already said around the discussion, which we did not stray into the area of the radiology more, but more at the home device or device that a patient would take with them, that kind of medical device.

Christopher Ross – MinuteClinic – Chief Information Officer

So if you're looking at home device, I just think home test and simple physician office diagnostic stuff would be really useful. I know I've messed around with some of that in previous lives and it's a very messy domain.

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics

Thank you.

John Halamka – Harvard Medical School – Chief Information Officer

Wes Rishel, last word on this one?

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst

Thanks. So I think about these kinds of devices or medical instruments in sort of three groups: those that are used in the hospital or a large clinic; those that are used in the home by a clinician; and those that are used in the home by the consumer without a clinician present. It strikes me that there are substantial differences in the workflows, in the way that the data is integrated back into managing care. For example, I know that there are major vendors of communication services, cable providers and phone companies, that are looking to be able to provision and deliver a device to a home for a patient to use and take responsibility for first line of support and things like that. Those are issues that don't come up when a nurse brings it into the home or something like that.

I don't know how much you want to focus just on some very specific issues like device identifiers and things like that, but to the extent you can organize the panel so that you get experience across those range of uses, I think it would be very helpful.

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics

Very good. We had not talked about the introduction of, for example, like you said, someone who's bringing a device into the consumer independent of what I would say is kind of a medically-oriented or clinically-oriented introduction or orientation to the consumer. So it's a very good point.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst

Liz, I think there's a pretty good body of experience out there now, so I think this is sort of the idea time. People have been through the first round of trying to make it work and they haven't quite settled on the solutions yet.

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics

Thank you.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences

The fourth is the situation where you have a device in the home that is queried by the provider, which also has major interoperability issues.

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics

Yes, it does. Good point, Dixie.

John Halamka – Harvard Medical School – Chief Information Officer

Great. Thank you. A very rich discussion there. So the remainder of our time is going to be an update on the Direct Project and an overview of the S&I Framework. The comments that I will make are purely going to be introductory to the S&I Framework, so I'll do those right before Doug's discussion. So, Arien, as you're queuing up your slides, while we have been sitting here, the Beth Israel Deaconess Direct Gateway has sent my entire medical record in both CCR and CCD form to my direct email address, which is jhalamka@direct.healthvault.com. It has been received and placed into a data atomic form in my health vault records.

M

Does it include Lyme disease?

John Halamka – Harvard Medical School – Chief Information Officer

It does. It includes AD nodal reentry tachycardia, Lyme Disease, glaucoma.

W

...privacy.

John Halamka – Harvard Medical School – Chief Information Officer

I'm not patient zero. Arien will give us the update on others, but just to give the other experience, it took one day to download and install the open-sourced version of the software, configure it, get appropriate certificates generated, and begin transmission.

Arien Malec – ONC

That warms my heart. That's great. Thank you.

John Halamka – Harvard Medical School – Chief Information Officer

That's multitasking.

Arien Malec – ONC

That's right. And orchestrating the multiple aspects of the PCAST Workgroup.

So that's a great intro. Thank you for having me here. I'm going to give you a brief update on the Direct Project. We want to spend most of the time on the S&I Framework. I think we'll spend, if you go to the next slide, more time on the next meeting. We set the expectation that the Direct Project would be reporting back to the Standards Committee on experience and utilization.

So the big news for the Direct Project is first production usage. And we've seen a number of instances of ...usage. The first instance was ten months, more or less, after the start of the project. We got immunization data from Hennepin County Medical Center to the Minnesota Department of Health using the insurers, their HISP. One of the neat things about that, besides the fact that it's one of the meaningful use criteria, it's actually overachieving on the meaningful use criteria because I actually got the immunization registrant to accept and incorporate the data, is that the same transport allows Hennepin County Medical Center to take the same immunization data and send it to patients so that they can send the immunization data both to the Public Health Department, Minnesota Department of Health and to the individual in support of their own self-management and all the reasons that we need to have access to our immunization data.

The existing instance of a personally controlled health record that has a direct county is Health Vault and I know that Health Vault has tools that enable consumers to get reminders and other kinds of services based on the immunization data that they have access to. So that's, I think, one of the reasons we designed Direct to be content neutral, to be universal transports so that you could implement once and then reuse the transport across multiple use cases.

Second example was the sending of a summary care record in transition of care. Dr. Al Perini and the Rhode Island Primary Care Physicians Cooperative, using the trust framework that had been adopted and a lot of the hard work that was put into this by RIQI, the Rhode Island Quality Initiative and in Preva as their HIT, one of the things that's interesting about this one is this was a patient of Dr. Perini's who was getting transitioned to I believe a GI. The GI doctor got the entire CCD, including the clinical history for the patient and was able to make treatment decisions for that patient. That same interface was also being used by RIQI to support under appropriate, a different privacy and trust framework to support push of that same record to the Rhode Island Quality Initiative longitudinal data store for cross encounter longitudinal quality management in support of the Beacon Program and in support of RIQI's ongoing quality improvement activities. So again, a good example of using the same transport in different context.

The second to last, so we've got two primary care, this is where we get acute care to patient on the Dr. Blanca example, primary care to patient with Dr. Palo Andre, theHealth Vault. What I thought was really fun about this one was that Health Vault implemented their direct address support and characteristics to implement their direct address support. There wasn't this celebration and orchestration of the first push. They just upgraded both their instances and all of a sudden Dr. Andre could push data to Health Vault.

So, some of the emergent properties here. And again, any other personally controlled health record that has a direct interface for patients, exactly the same workflow can occur.

We saw the inverse of that with Dr. Blanca in terms of any organization that can send via Direct, Health Vault can receive. So again, some of the nice attributes of making the transport independent of the content and ensuring universality in terms of the address in the transport.

We're starting to see a number of other significant announcements. So yesterday, for example, the AFP announced the AFP Physicians Direct in conjunction with SureScripts offering modular capabilities for AFP members and their colleagues. So we're starting to see a number of interesting, significant announcements in terms of interesting ways of using Direct to address the healthcare, public health and hopefully soon also driving down costs through information exchange.

I think we'll see more at HIMMS next week. And we look forward to the increased usage of the Direct Project specifications to address key business concerns and key health concerns across the country.

So other updates, we've got great review in December from the Private & Security Workgroup. Really helpful comments addressing some of the messiness in the specification, also addressing some concerns in terms of optionality. We've done a full rev of the specification in ways that we believe address the concerns of the Privacy & Security Workgroup. And the final specification is in its last days, minutes, hours of concensizing. We have a consensus-driven process and I expect that unless there's major debate about what we call the thing that does the activities, there's crossing of T's and dotting of I's, I believe that we'll have consensus to prove specifications for the core Direct Project protocol.

Then as I mentioned, we're collecting utilization metrics, usage findings, lessons learned, experience reports, really to provide as a package back to the Standards Committee. As we noted, I forget how many months ago, that we were targeting the March 29th Standards Committee meeting to essentially say the Direct Project has completed its active work. We've got utilization work that's on the way. It also gives us a good opportunity to give all the lessons learned and feedback to the Standards Committee for evaluation of the specification in terms of recommendations to HHS. So we're gearing up for that very important milestone and look forward to that activity. So that's the brief Direct Project update.

John Halamka – Harvard Medical School – Chief Information Officer

And Judy, just to confirm, I have the Standards Committee in March as the 16th, not the 29th.

Judy Sparrow – Office of the National Coordinator – Executive Director

I think you're right, but I'd have to double check.

John Halamka – Harvard Medical School – Chief Information Officer

So if you could do something by the 16th, that would be great.

Arien Malec – ONC

Thank you. I think I looked it on the calendar, but I could have been completely wrong. We'll get that right.

John Halamka – Harvard Medical School – Chief Information Officer

Very good. Questions that folks have for Arien about the Direct Project? Just so everyone understands how Direct is implemented, so I chose to implement it using this open-source approach where it is sent via an SMIME, encrypted package over regular SMTP between ...the hospital and in this case Health Vault the PHR provider, whose SureScripts is implemented is slightly different. That is that they may have various vendors that interface with the SureScripts network using a ...protocol, which then uses the SMIME approach to send data out using the standard specifications. So in a sense we're achieving an ecosystem, which is, as we had said early on, we looked at S..., and ... and SMIME and everyone implements at least the SMIME protocol. And what they do behind the scenes is left a bit up to them.

Arien Malec – ONC

We definitely want to see innovation and see organizations competing on quality of service, competing on workflow, competing on the best ways to incorporate this into their HIT products, into their EHRs, but make sure that there is at least a common standard way for anybody to reach anybody. And that level of commonality makes sure that we don't have vulcanized areas or vendor lock-in. And the reality of many areas, I take the area that I come from in the San Francisco Bay area, within a 10 mile radius of where I live there are any number of organizations that have implemented data sharing and information exchange in their communities on completely different stacks. We have Kaiser in the area, we have a pooled network of a number of providers, we have a standard...HIO. It goes on. We have a number of Epic installations with Epic anywhere. It goes on and on and on the number of networks that are in the same geographic area and the number of transitions of care that crossed all those networks. So having a common layer in between all of those helps us achieve the goals that we're establishing for meaningful use.

John Halamka – Harvard Medical School – Chief Information Officer

Great. Other comments? Chris, any comments to make?

Christopher Ross – MinuteClinic – Chief Information Officer

I think maybe just from the standpoint of participating in it, I think John's comments about sort of the ways people are innovating and Arien's comments about what you want to see, I think Direct is really important. From where I'm sitting, Direct is really important in and of itself, but it's also really important in what is catalyzed in terms of additional thinking about how to do exchange, just the way you described it. So, congratulations to the folks who have been working on it. Especially you, Arien. I think it's really been a remarkable achievement in such a short period of time.

Arien Malec – RelayHealth – VP, Product Management

We also always have to give props to the fathers of Direct in terms of Wes and David.

Christopher Ross – MinuteClinic – Chief Information Officer

Absolutely. My mistake. My oversight.

John Halamka – Harvard Medical School – Chief Information Officer

Linda and then Rick.

Linda Fischetti – VHA – Chief Health Informatics Officer

Just an observation, for two consecutive meetings we've had these gentlemen come and give us an update on NW and Direct, and ...interoperability. And next time you come, it would probably be very helpful to have an update on NWHIN exchange as well, because those pilots are lighting up and going forward.

John Halamka – Harvard Medical School – Chief Information Officer

Thank you, yes. I see we have the co-fathers. So ...

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst

So two questions. The first one, one of the key points early on in all this was to separate the handling of the transmission of the data from the standards for how the data is packaged internally. And I guess the question is, after considerable debate it now seems self-evident that that was the right thing to do. What's given up in the process by separating those two?

Arien Malec – ONC

That's a great question. The observation that I have is that in every instance of Direct that I've seen, the debate moves very quickly from transport to workflow to content. There is a level of indirection that needs to happen when you receive a package to figure out which part of the workflow it needs to get deeply integrated into. I think we all know that when physicians use electronic health records, workflow is incredibly important and workflows that are clumsy or ineloquent or don't fit clinical thought process just don't get used.

We're starting to see some notions of special purpose addresses – lab data goes to this address, referrals go to that address that have some expectations in terms of what kind of content they need to receive. But if I open a general purpose address, I'm going to need to figure out what content is inside and then do the appropriate thing, and that appropriate thing may end up having a "well I give up, I need to forward it to human to catalog" because that thing is not a healthcare content or not a healthcare content that the receiver understands.

There are, as I think people know, there are specifications like the IHXDR that have built in metadata that help that workflow process happen. And we've deliberately sacrificed some of that rich packaging for the ability to have a transport protocol that can be used under multiple guises and multiple scenarios. There is the option for people to use the same rich content and package in a specification called XDM, but we don't mandate it and a receiver would have to figure out, we'd have to expect to receive something that isn't packaged that way. So there's definitely a downside and an upside. So the upside is same transport, multiple workflows and from a bespoke VP end kind of connection that you may need to have with two or three or ten or twenty of your colleagues in clinical care, we can get that down to one that's

universal. The downside to that is that you need a little bit more flexibility in terms of figuring out what you've got and incorporating the workflow appropriately.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst

Thanks. In what circumstances is the content completely blind to the ISP here?

Arien Malec – ONC

That's a good meeting question. Thank you. Because of the specifications that we're using, we're essentially using standard SMIME, the sender and the receiver themselves make the decision in terms of their business associate agreements or arrangement in terms of where the point of encryption and the point of decryption rests. So they make independent decisions about where they do the encryption and decryption, and how much they choose to expose to business associates of theirs versus not. So it is absolutely possible for organizations, and my understanding is that Beth Israel Deaconess is doing just this, organizations to take the encryption and decryption step entirely within the walls of their organization and make sure that intermediaries of theirs have access to only the encrypted content package. Organizations that have less sophisticated capabilities or who have a need for mapping services or other kinds of services within appropriate business associate agreement can delegate that to the contractee of that organization. But if a physician or a covered entities' decision about to do that or not to do that, there's nothing forced by the transfer protocol that make them outsource that activity.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst

Okay, one of the concerns that people have expressed early on is they're going to have a really easy way to send incompatible data. What are the people who are going live doing about being sure that they can speak the same language with regards to the package they sent?

Arien Malec – ONC

Typically they are just like any other end to end system. They're ensuring end to end capabilities. So, for example, between Hennepin County and the innovation registry, they're ensuring that there is a standard, a true to standard version of HL7 2.5.1 immunization specification that they're sending to the immunization registry.

I think we'll see some services that will do content mediation. If you look at any value added network, there is often a need as a business service to be able to do that. But the decision to do that or not to do that and to expose the PHI that gets exposed in that process or not to do that is, again, under the covered entities control and gets done under a business associated appropriate agreement.

John Halamka – Harvard Medical School – Chief Information Officer

David?

David McCallie – Cerner Corporation – Vice President of Medical Informatics

After all of Wes' hard questions, mine is much more lighthearted. I just want to congratulate and thank ONC for having the foresight to hire Arien and put him on this task, because the good idea wouldn't have gone very far without Arien's insistence on convening us to keep us moving. He really did an amazing job of ruffling over some friction at the beginning when we had different ideas about what to do. The fact that he was there and able to do it and paid for by the taxpayers money, that was a great win for all of us. So I really appreciate it as someone who watched this very closely.

Well, that's not lighthearted, that's really sincere, but on the totally lighthearted moment, Aneesh in his kindness cited Wes and myself on his post on the White House blog where he described this announcement and this made me a great hero with my children. They're already arguing about who should play me in the movie.

Arien Malec – ONC

I'll admit that my daughter said, "Yes, thanks dad. I'm going to go play with my friends now." First of all, thank you for that. I have been enormously humbled to work with a really amazing community and I can't say enough how incredible the community that came around the project was and how many decisions

people made to swallow their desire for a technical solution and move forward, and the amount of leadership and innovation and just incredible thought that's come out of the community. So back at you, I guess. Thank you.

John Halamka – Harvard Medical School – Chief Information Officer

Great. Well, Chris and then we will move on to our next topic.

Christopher Ross – MinuteClinic – Chief Information Officer

In the midst of this love fest, it's probably not the perfect time, but good enough time. We really ought to extract lessons learned out of the Direct Project. I know we had a great review process that was chaired by Dixie and I think that did help improve the spec and that was good, but there's some really interesting things that came out of Direct. And since we're about to talk about S&I, I think there's really lessons learned that can be pulled from one to another, and I would offer up things like you look at Wes' questions and the answers to them, I think one of the magic of Direct was that it did everything that was necessary, but didn't try to do everything sufficient. It didn't try to spec everything. It's a specification on which people can then expand and do some interesting things. But they didn't leave off anything that wasn't strictly necessary. Right? But didn't try to overreach and go for everything that was sufficient to do absolutely everything.

And I think we're seeing in the implementations that you described here and in other kinds of places that different entities are going to be able to interact with the spec in different kinds of ways. So I think one of the things that's interesting about it is it's an opportunity to provide more control to a physician, for example, as opposed to institutions in some instances. So an individual physician has some options here on different levels of connectivity that may not have been possible before. To say I'm the doctor, this is the way that I want to communicate with my patients; maybe I want to use EHR or whatever else. So I think I'm off the rails at this point, but I think it would be really worthwhile for us to try to do a systematic kind of what went well with Direct and how could that apply to future standard development in stage II and III.

W

I really appreciate all the work, too, and I want to read some famous words we've heard many times today and yesterday. Thank you for your more boldly pursuing to ensure that the nation has electronic health systems that are able to exchange health data. I am just having a little problem with the past day and a half versus today and your progress and the attempt of PCAST. And this sounds like a closing comment – good job, well done – but why wouldn't they be the logical next move to PCAST to look at some of the opportunities that have been mentioned? I'm just a little confused that there's such a separate and diverse topic and discussion. This is such a successful talk.

John Halamka – Harvard Medical School – Chief Information Officer

Right. ...as we talked about a youth case where I raised this immunization idea this morning, you can imagine that by having providers send data via Direct to a repository, this is the perfect example of a push use case. PCAST has said it is one thing to get data in and out of reform, pushing to an ...point; it is another to pull it. Well, Direct doesn't cover the pull use case. That's a different set of work.

W

I'll bet if we gave them that task, they would accomplish it.

John Halamka – Harvard Medical School – Chief Information Officer

And so what you're talking about is process.

M

....

John Halamka – Harvard Medical School – Chief Information Officer

And so I think what has to be said is we all have very rich discussion on how to do this in a step-wise manner, which step 1 was let's all push and that's really what stage I and II is about, and then let's all pull, that's what stage II and III is about, so we'll get right on that.

Let's move on to the S&I framework discussion and let me start off with a preamble. So many of you have chatted with me and said, "You know this S&I framework, I am suspicious. There are many things this thing could be and we're not quite certain how the HIT Standards Committee should articulate what's the S&I framework." So, for example, should, as I mentioned when we started the meeting, we do the heavy lifting of the bits and the bytes and the convening of all of the SDO's and right implementation guides or should we come up with characteristics and make sure we are engaged at the beginning, the middle and the end of the S&I process to advise what should be done to do a mid-term check in as to what is being done and to evaluate what was done. And so the Direct Project very successful, but let me point out a process issue, which Arien will disagree with, is that Dixie was asked to evaluate the finished product or near finished product as opposed to get involved at the very beginning to articulate its desired characteristics, do a mid-term check in and then do an evaluation. So hence, I think we've learned that there are ways that we may want to work together that will make everyone of us feel better.

There are many RFP's associated with the S&I framework; one of which uses the word "MIME and IEPD" a lot and some people reading that RFP might say, "Ah, what this is going to do is eliminate all work done to date, all SDO's in existence to date will be ripped and replaced and we will replace their artifacts, HL7 or other type schemas, with IEPD's and MIME XML, and so this is in fact a nefarious scheme to diminish the role of SDO's and the rich tradition of the interoperability that we've all worked on for 20 years." Don't worry, this is all going to be addressed in this slide. So I'm just leading up to what are some of the concerns.

As ...find work on developing the scripts that we all use for certification, I think a number of us have gone through the scripts and said there are ways those scripts in testing, you couldn't have known it ahead of time, but then sort of they rolled out could probably have been polished a bit to reduce some burden. How do we, as part of S&I framework, which is really going from requirement through harmonizing standards to implementation guides to testing to production of risks, artifacts and tools, make sure that we're closing a loop, so that if there are such things that can be polished or improved, then all the other stakeholders know about it.

There are a number of projects that are currently kicking off through the S&I framework around things like transfers of care, CDA, cleanup and lab cleanup; how do we ensure those projects have the appropriate feedback and oversight like Dixie's group had that feedback to the Direct Project. And how do we ensure that vocabularies and code sets that we also care deeply about are appropriately incorporated into all the S&I efforts, realizing that many people in this room have done foundational work in vocabularies and code sets and their expertise really needs to be lent to the process. Because the last thing that we want is a number of 23 year olds from consulting organizations writing a whole set of artifacts and repeating the sins of the last 20 years that many people in this room have learned long, hard lessons to avoid.

So that was a five minute summary of every concern that every one of you have articulated to me and Doug, in response, has put together some slides to serve as an update and response to some of those concerns so we can move forward together.

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability

Thank you. In fact, I have a slide that goes through all of the sinister plans. So when we get to that, we can update that.

So at the last meeting that we had, we had in December talked about some of the initiatives that we had on the list. We got some feedback from this group and we announced them just before the last meeting and we sort of operationalized them just after the last meeting. So we don't have a whole lot of data to show you, but I do want to give you an update and just a reminder of some of the things that are out there. And we hope to be able to have continued engagement with the HIT Standards Committee as we think about new things that we need to be working on to help meet the needs, not only of the standards

that have already been adopted and that need to be sort of refined, but also to look forward to stage II and stage III of meaningful use.

So there's been three initiatives that have now been fully launched. The first one we're calling the CDA Consolidation Project. What this is trying to address, it brings together HL7 and IHE to solve what we're calling the "onion" problem. This notion that you have to go from the specification of the ...to the template for the C83, which references an IHE protocol and try to make sure that we've got consistency across that. One of the things that I think is exciting about the CDA Consolidation is that they are beginning to explore something called "green CDA," which is an effort to simplify the information that gets sent across the wire. Still having it mapped into room structures and things like that, but across the wire from one system to another to simplify the way that exchange occurs.

The second one that we've announced as well is something called Transitions of Care. This is to take a look at the CCR and CCE, the transitions of care standards that we have, and to begin to refine those and get them down to a level of detail that isn't just a document, but starts talking about molecules and about standardizing the components of that, making sure that we have appropriate value sets and making sure that we get to the point where we have a robust description of a CCD that in collaboration with ...we can test people and that if they pass the test we can in some sense help to assure interoperability. Yes?

(Can't hear question)

I think a lot, how can I answer this question in a tactful way. We are obviously awaiting some of the alternatives that we will get from the HIT Standards Committee and the working group on PCAST. One of the intentions of the S&I Framework all along was to make sure we had consistency across different standards, so that demographics represented in one standard was the same as demographics in another. And not restricted just to HL7, but to look at other kinds of standards, like X12 and CCD and CCR. So in some sense we've had the intention all along to make sure we had clear, composable elements within the standards and so this is certainly aligned with that, but it's something that we've been thinking about for some time now.

John Halamka – Harvard Medical School – Chief Information Officer

If I may add one thing, it's really an attempt at a transitional ground to say that we heard a lot the last couple of days about a document-centered view and the importance of that in terms of the clinical context for the data. I also think that we know and particularly see reflected in the draft stage III meaningful use requirements that we want to get up to date medication lists, up to date problem lists, and that one way of doing that is to make sure that the information that is transitioned at each transition of care can be moved appropriately with appropriate clinical decisions to help inform that up to date process. No one wants to naively take a med list and slam it into another med list and say that's the up to date med list. But if you can't take the medications out of the document and use them to inform essentially cognitive support for the provider who's trying to get the up to date med list, you've left a lot on the table in terms of interoperability.

So that's the extent of the molecules of exchange is to help do the appropriate cognitive support for providers and other care professionals who are trying to get the up to date view of the patient out of the document.

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability

And it's molecules as opposed to atoms or subatomic particles.

The last of the initiatives that we've announced is a laboratory interface improvement, and the goal there is to bring together at least two of the HL7 standards that we have and to get some clarity about when to use it and when not to use it and can we reduce the costs and the time for new interfaces to be constructed. So this includes participants who have been proponents of eLinks as well as proponents of the HL7251 specification for labs, and to see if we can't come to some agreement about how those are related and if we need to reduce the cost and time of these interfaces, make them easier to implement

and also be able to have them used in different settings, bringing together this particular group to help us out.

So we have a pretty robust initiative commitment membership for each of those. Obviously, we turn to this group to help us. I think one of the lessons, and to Chris' point, one of the lessons that we learned in the Direct Project is that the success of these are driven by the community. And that if we have highly motivated, engaged people participating in the initiatives, we get a much better product at the end. And so this is something that we want to be able to support and to stand up, but we don't want to be the ones who are driving everything that happens, because the better product is going to come from the engagement. And you may see this every time we come and talk to you is that we really want to have people participate in these, because we think we're going to get much better value out of that as well.

This is just a graph of the registrants on the wiki. So on January 10th we had approximately 50. We have over 350 people that have registered with the wiki at this point. The other graph there represents those folks that have committed to participating in a way that they will implement or use the things that come out of these initiatives. And so the CDA Consolidation, the laboratory interfaces and the transitions of care, all of them are represented there on the graph.

So of those we've gotten good participation in the transitions of care; good participation in the CDA. We're lagging a little bit in the laboratory interfaces, but we hope that people will engage and find that something that would be useful for them to participate in. If we get no commitments, then we just cancel the project and move on. But so far I think we can proceed.

So, John has sort of introduced this slide for us already. The S&I Framework is a sinister plot to undermine the FDA. This is certainly a criticism or maybe a constructive suggestion that people have given to us. I think what's important is what we're seeing, and particularly some of the activities that are going on with the green CDA project and the HL7 IHE project, is that we would like to be there to help support the standards development community produce high quality standards that can have a broad participation and really drive towards the kind of cross fertilization that we would like to see. So this is not a sinister plot to undermine the SDO's, but in fact of the initiatives that we have undertaken that this point, all of them represent where we have more than one standard for a particular set of problems or we've got the need to have two different standards organizations work together to come up with common solutions. And so we hope that this is not seen as a sinister plot and we will do what we can to help prevent that from occurring.

The second thing, the framework is a sinister plot to demonize healthcare. One of the things that I think is important, and I've tried to emphasize this, is that one of the things that we found useful in looking at ...was the process but not necessarily the model. There are things that we need to add in and leverage from other existing models that are out there. Mean doesn't have within it any information model embedded in it. That has been the criticism that we've received. But it also means that we are able to take the best and bring that into the process.

S&I Framework is a sinister plot to apply abstract informatics models for no good purpose. I think this was one that you had raised as well. I think one of the things that we learned in the Direct Project, and I think we want to carry on through this, is that organizing and harmonizing across lots of different use cases and lots of different standards is a complex and difficult process. We could have endless amounts of committee meetings to try to come to some consensus, but that in fact if we choose agreed upon and targeted goals for what we want to accomplish and we drive towards that, and I think Arien has demonstrated tremendous leadership in creating that concrete deliverable, if we use that, I hope that we don't have abstract models. I think abstract models, we can't test them. We can't tell if they're right because you can't get them out there and see if they solve the problem that you want it to. And so our goals throughout this, and this group here will help keep us accountable, that what we do in the S&I Framework and how we support the various initiatives should drive towards the value that we'd like to see.

A sinister plot – to pay 22 year old consultants to relearn all the lessons of the silverbacks/gray beards – we didn't know which of those terms to use – and have them reinvent the whole thing over again. I said this before, I hope if we make mistakes – and we will, make mistakes – that we make new ones, not old ones and that we learn from the folks around this table and other places that can help us. We have to figure out the best way to do that, and I guess the best way that I know is in an open ended, transparent way to engage those people who are experts and who can help us get this better.

Now, some believe that the S&I Framework is all of the above, and so I hope that isn't the correct answer. In fact, what I hope is that the answer is none of the above. The S&I Framework is really intended to be consensus driven, community oriented and focused on a mission to work with the SDO's in the standards and vocabularies that they produced; to create the implementation package in support of a national priority that includes meaningful use. And so we really are trying to find the right way to work with the communities with the SDO's and provide a place where people can come and collectively solve a lot of these problems.

You've seen this slide before, it really talks a little bit about the way in which we have to organize and we have our healthcare community, we have federal partners, we have the HIT Policy Committee and the Standards Committee. We have standards development organizations. And I think John is absolutely right, when we think about engagement, one of the lessons that we've learned from the Direct Project is that we do well by engaging you early and getting feedback early, because there's a lot of smart people around this table; making sure that we have check-ins, that we're on the right track, and at the end make sure that we've stayed on track and got to where we wanted to go. And so we're trying to figure out how we're going to manage all of this internally with our contractors and things like that.

One of the things that I said to my contractors is that success for them is a 1:10 ratio in the sense that for every contractor who is on a call, there should be 10 individuals in the community that are contributing to the effort. And if what this becomes is just the people who show up are going to be the consultants, then we need to figure out what we're doing wrong and how to improve that so we can engage people more effectively.

I think it also provides a way for us not only to coordinate with these folks, but to coordinate across our federal partners. One of the important federal partners that we work with is NIST. I think having them engaged in this process early and having them be able to be at the table when we're thinking about use cases and we're talking through how to do the standards or the specifications I think is going to give us a higher quality output at the end. And I think it will help, John, as you've blogged about before, keeping those things aligned, so that we're able to really get high quality testing associated with those high quality standards. And this provides a framework, a way for us to sort of have that kind of coordination as well.

We've got a lot of work to do. I have, I call it the scary list, where we've gone and we've taken a look at meaningful use stage II and stage III, and we've sort of extrapolated what it is that we need to do to get there, and there's a lot of work. There's a lot of work that we need to do. And so we are going to continue to do that. I think one of the things the HIT Policy Committee has asked the Standards Committee is to look at certificates and directories, so that certificates can be interoperable. It's an important part of the direct infrastructure, it's an important part of privacy and security, and that is a key goal and a key initiative that we want to support within the Office of the National Coordinator. In addition, we have to have directories, and that's essentially certificate discovery. How do we find people and the kinds of keys that would help us have that secure transaction?

There are some draft meaningful use stage II recommendations. They include many implicit and explicit asks, and there's a lot of work there that we need to do around vocabularies and terminologies, as well as refining some of the standards that we currently have. And we hope that we can offer the S&I framework to this committee and to the folks that are trying to solve problems as a streamlined process, a working model that will help us all achieve that vision.

Now, I don't think we have everything perfect just yet, and I think we're trying to improve the governance, we're trying to improve how we organize things, but I think by keeping in close communication with the

folks around this table, I think we can get there, and do so in a way that, I hope, helps all achieve the mission we've got.

John Halamka – Harvard Medical School – Chief Information Officer

Before we go to the next slide, one addition that I have to this slide. I think everyone recognizes this, but may not have the gnawing in the pit of their stomach in the way that I do and the way, certainly, that Doug does. If we assume that ONC is going to follow, and CMS are going to follow more or less the same timeline for stage II that was followed for stage I, and it's the office of no Christmas, and there's an NPRM around this same timeline as there was for stage I, there's a regulatory process that I won't profess to understand in depth that requires clearance, that requires regulatory writing, that requires a lot of upfront activities. Which means that any of the raw material that wants to be in that update to the Standards of Certification rule has to be pretty well baked by, say, the start of November, the end of October.

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability

Sooner than that.

John Halamka – Harvard Medical School – Chief Information Officer

Sooner than that; beginning of October. Which means that when we look at this list of activities that the Policy Committee is putting out in terms of their draft criteria for stage II meaningful use, and we need to get those translated into actionable certification criteria for EHRs, there is an enormous amount of work between February and October that needs to get done along a wide dimension, a large dimension of activities. So we've got the folks around the table here. We've got the contractors in the S&I framework, we've got the broad healthcare community, federal partners who are ready, willing and able to work on these problems. We just need to make sure that we're harnessing the power and the energy to get a lot of stuff done very quickly.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Well, thanks very much. I think you have done a very nice job in addressing some of the more central concerns. Let me summarize. We've had a lot of discussions today about assignments to our various work groups and committees, and here's just a thought. Taking everything that you've said and everything that we've discussed today, it's March 29th. There was a mistake in my calendar; we checked the ONC Website. On March 29th, per the commentaries just made, what I hope we can do is look together at the work we must do until October, and figure out how to, with the S&I framework and work we have to do, parcel it out in just those few months.

We know at the very least that our quality workgroup is going to be reinvigorated. It's going to work on E measures and do QDS education. Our Privacy & Security workgroup will be working on provider directories and certificates. The ops group will be working on devices, as you heard, and will likely also get the assignment of patient matching that we've just been given. And it seems as if that ops group would also be the right place for the S&I framework articulation on the three projects that you currently have, because lab and CDA and transitions of care is very, I think, the domain of that ops workgroup. And the implementation workgroup, I think there may be a close the loop issue as you get to the test scripts, so that the implementation workgroup, very sensitive as to the impact on the community and barriers and accelerators. So if we agree that the whole committee will work with you on timing, and that we will parcel out these tasks, these subcommittees, with especially the S&I framework first three projects getting a much tighter linkage to clinical ops and making sure that the end test scripts are also linked to implementation, it seems like we've built a working relationship.

Now I want to open it up to the rest of you, because I'm sure you have thoughts. So David, is this a new comment?

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Sure. Let's see, where to start. The first is a political question, and then I have a real question. So the political question is not so much—I think you've covered the sentiment in your bullet points of what S&I frameworks isn't, but the sentiment that I get back from people that I talk to that are aware of what's going on is this sort of question of about how six or seven different contractors can possibly work together and

not create another onion skin. And to your bullet point about a bunch of 22 year-olds relearning all the mistakes that have already been made, I'll just register that that's the most consistent issue that I hear when I ask people about S&I; just a concern as to how is that going to work with a whole bunch of different contractors all with their hands on something. So I don't need an answer. I'm sure you know that; you've heard that. You had it, essentially, in your slide. But that's just something that comes up.

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability

Well, let me just say this. We fail if it's only the contractors. And so we can encourage, we can cajole, we can beg people to participate. But if it's just the contractors, we haven't advanced at all. And so that's why, to me, it's so critical that we have folks involved. And quite frankly, we have the ability now to task people, the contractors, to do things, and maybe help us move things more quickly. But for those folks who don't want this to be run by contractors, there's a wiki to sign up on, and there's projects to participate in.

John Halamka – Harvard Medical School – Chief Information Officer

And I think that's the main answer. A sub-answer to that is that one of the things that we've been talking about, and that all the contractors agree with, is that we want contractor performance and mission performance to be aligned. And mission performance is, by definition, out of the immediate hands of the contractor. But we want to make sure that we don't have a process where contractors are saying, yes, everything is good, and yet we fail on the end stage. So we're trying to make sure that we're aligning contractual performance and mission performance together.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Thank you for that. My more substantive question, it actually triggers off of that. I got an e-mail recruiting more participation in the CDA Consolidation group last night or the day before. I finally got around to reading it, and there is so much stuff going on around the question of CDA and reworking the CDA versus whatever the PCAST Report is hinting by its damned by faint praise non-endorsement of CDA. With Health Story and with templates that Jamie's group is working on, how are you going to scope that so that it's feasible to produce something in a timeframe, like you said, by October? It's an immense problem; or not, depending upon what you choose to cut out. But I was asking Kevin Coonan, who was sending me the e-mails, what is the scope of what we're trying to do? I'm not—

John Halamka – Harvard Medical School – Chief Information Officer

Sure. The scope is actually very narrow. There's a wider scope that HL7 and IHE and Health Story are engaged at, and we're supportive of that scope. But in terms of the ONC resources and the mission that we're focused on, it is narrowly targeted, A, at the C-32 and all the sub-layers of the onion; and B, at the current set of ... criteria or data elements that are associated with meaningful use. So it's a narrowly targeted scope, targeted, really, I think one of the major pain points that we've heard a number of times to address. So it's not everything, and it's not everything that HL7, IHE and Health Story want to take on.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

And it's not the green refactoring, necessarily? Or would that be in scope?

John Halamka – Harvard Medical School – Chief Information Officer

The way I think about this is that if part of what we want to do is provide essentially a bug fix specification to the community around stage I meaningful use, that's probably not going to be a green CDA, because that's a lot disruptive in the short term. If the community comes back and says, and here is a way of addressing specific terms and simplifying the approach in ways that do have maps back to the full CDA as a green CDA project, I think that's something we're likely to take in transitioned care and look at as a very positive attempt to approach or address the need for simplicity. Chris?

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer

Can I put my card up as well? This is Stan.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Sure.

Christopher Ross – MinuteClinic – Chief Information Officer

Thank you, Doug, and I feel badly that the sinister plots have been unveiled and aren't real. It was much more fun to think of it that way.

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability

I think the success, though, is that we had agreement that there was a sinister plot across all of those.

Christopher Ross – MinuteClinic – Chief Information Officer

I want to ask a strategic question. It seems as though much of what the S&I framework is doing, whether it focuses on recasting CDA, whether it focuses on, frankly, PCAST infrastructure or even the I-word in interoperability, is on messaging and exchange. And I submit, that was probably one of the shortcomings of HL7, which focused primarily on exchange. To what extent are we, as a standards committee, S&I framework as an initiative, going to tackle the strategic issues of how do we represent shared modeling and information of information, not for its exchange, but for its conceptualization? I'm sorry, I'm a fan of abstraction. I think abstraction is actually good for you, because it can drive practical interoperability and interchange. And if we try to focus after the information has been generated and has moved through sources, and try to standardize it at the interface level, which is a good tactical plan. I'm not suggesting that we transform healthcare overnight from the inside out, but I think it prudent that behind that goal for interoperability and exchange, we have some glimmer of a notion of strategically how we should have a shared conceptualization of these elements that we're working with beyond the relatively trivial use case of information exchange.

So where in this interoperability activity or process is the—we talked about it this morning in the PCAST Report a little bit. Where is this notion of trying to harmonize, or even generate, a shared information model or set a somatic relationships or whatever we want to call it, that can, in turn, inform and drive the exchange metaphors?

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability

I think, and you know I like abstraction, too. We have our classic Stanford joke about that. But I think we have other programs within ONC, of the two are participants under the SHARP work, that we have not done a good job yet of figuring out how to leverage and merge that in. I think you're right. I'm looking at October and thinking what we need to do for stage II. But obviously, if we can get the conceptualizations that we have within the S&I framework, the information models that are supporting those, and begin to coalesce or harmonize, and to think ahead towards standardizing our standards, if you will, creating governance and process that allow us to have others consume what we produce and to consume what others have produced in terms of creating these harmonized information models, I think that would be good work to do. I don't know if we can get it done in the next six to nine months, but I think that's one of the things that we need to do to think, as you say, strategically. And I think that's going to involved engagement with our SHARP community. I think the silverbacks and the grey beards will have to help us with that, and make sure that we take the best approaches and learn from what has happened in the past. I guess I'll stop there.

John Halamka – Harvard Medical School – Chief Information Officer

The one addition I'd add to that is that if you think about the classic innovation funnel, we are, I think, avowedly at the narrow end of the funnel, just because the timelines for meaningful use are so acute. And we recognize that we're all at the narrow end of the funnel and that the stuff that we need to be doing to fill the wide end of the funnel is really the strategic need to make sure that we've got stuff that's in the narrow end of the funnel for stage III, and then for beyond. It's attention right now because everything is very acute and we've got the tyranny of the urgent right now and it kind of is what it is. But we recognize that there is an innovation funnel and we have a need to fill the wide end of it.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Stan, on the phone.

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer

Yes. I think that there are still questions that I have, and certainly it's not an ascription of ill intent. But I would characterize it in this way. Changing the typical three-legged stool metaphor, the issues that you have in producing standards are trade-offs between quality, speed and openness. And so what's still not apparent to me is when those conflicts arise, which I think they will, and in fact, the discussion that we've had so far of "the tyranny of the urgent" I think is exactly on point. So what happens? What are the details of governance in this process?

So at the one end, when everything is working well, and we have time, this actually is a fantasy world, because I don't think this one actually exists. Things are working well, HL7 is doing green CDA. That meets the schedule that ONC has for deliverables. Everything is cool. When things change, and ONC recognizes a gap, and the standards body, in fact, may not have that on their agenda, or they may have it on the agenda, but the timeline now stretches out to the usual open consensus standards process of a year or two years, answering each negative and going through each design and iteration, then what happens?

My suspicion is, and this is the part that I haven't heard articulated, is that when you're up against a deadline, and the standard open ... consensus process is going to be too slow, it seems to me what's going to happen is that the decision-making is going to be then taken internally into ONC. After all, you have to control your own destiny, and you're going to make a new standard that is now less open, but certainly faster than what could have been produced through an open ... consensus process. And so when there are conflicts, that's what's still not apparent to me. What happens then, and what are the opportunities? In spite of the fact that we would all have a chance to say what we thought, it seems to me then we're down to ONC is going to make a decision. Our input, in terms of actual final votes on things, are going to now be in the regulatory process where whatever was decided is at a decided advantage versus other opportunities or other options. Because now you're in the situation where you need to prove, as part of an NPRM process, that what's being proposed is wrong or bad, as opposed to being in a more open process, where all opportunities can be considered equally.

And so that's my question, is when push comes to shove, and we're up against a deadline, what's the governance process? And how do you actually then see making decisions that keep ONC moving, and at the same time, don't put us in a box of basically now just responding through an NPRM process of the decisions that were made?

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability

So I think you articulate the problem that we face and the intention very well. We didn't have any glitches in the Direct Project, did we?

John Halamka – Harvard Medical School – Chief Information Officer

Everything went incredibly smoothly from beginning to end.

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability

So there, there you have it. Success. I think we have not yet encountered all the possible problems that might come up. I think, Stan, you articulate extremely well what the tension is. I think some of that can be driven through leadership, even using an open process, as we did in the Direct Project, to try to come to some consensus. I think this committee can help us with some of that as well. I mean, the risk, of course, Stan, is that you raise the issue and then in six months I come back and I say, here's the problem. You guys have to help us solve it. But I think the risks are real. We have legislative mandates around meaningful use that says we have to move forward and continue to advance. I am hopeful, and in fact, I'm encouraged, with my interactions with the Standards Development organization and HL7, is that the participants there get it. They understand the tension that we have, and that people are really rising to the occasion. I see no reason to expect that that kind of behavior wouldn't continue. And we will continue to do the very best that we can with these timeframes. But we will bring these back, I'm sure, as things go along.

John Halamka – Harvard Medical School – Chief Information Officer

And the other aspect of that answer is that this is not ONC and the industry as two separate activities. This is a group of organizations that together have a mission, and I think we need to be motivated more by the mission than by the process. I think we can all agree that if we, for example, can't reduce the time and cost of a new lab interface, we have failed ourselves and we failed the providers and patients that we serve. And I don't at all diminish or make marginal the very serious process issues that you're raising, but I guess the way that I would first approach that is to push that back on the community and say, are you in the mission? And if you are, what can we do to make sure that we can solve for openness, speed and quality? Because this is not about vendors in ONC and health systems; this is about us and our mission for the patients that we serve.

Jonathan Perlin – Hospital Corporation of America – CMO & President

I know we're running behind time. Do we have time for one more?

Judy Sparrow – Office of the National Coordinator – Executive Director

Yes, go ahead.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Okay, so Kamie, I know you've been waiting quite awhile.

Kamie Roberts – NIST – IT Lab Grant Program Manager

Yes, I just wanted to strongly support something Doug said and tie it in with one of your concerns, John. By having better specified standards, specifications, criteria, and implementation guides, writing the test scripts is a much easier process. So by starting out early and having this involved early in the process makes that much easier. And also I'll add that NIST does have somebody on the implementation working group and he's the lead for the health IT testing work NIST, so we'll have an easy interaction on that.

John Halamka – Harvard Medical School – Chief Information Officer

Wonderful. Thank you. Should we open it up to public comments?

Jonathan Perlin – Hospital Corporation of America – CMO & President

Before you do, let me just thank everybody. The last discussion was particularly important, and I'm struck with a question, and I think your answer is, and Stan, you're framing of the question was very good. I'd respond with a question, well, what is the alternative, particularly in the context of the legislation that overrides our activities? I think it's very sensitive. It's reminiscent of the discussion we had earlier, and difficult to separate the payload from the transport protocol and we need to make sure that both are effective and intact.

So this is a process that we're going to have to pay attention to. I'm sure it will be self-rectifying as we learn. There's an openness about the challenges of it, which is greatly appreciated. So I look forward to working with you, because frankly, even if everybody on this committee dedicated to trying to do that work, there are not enough hours in the day. There is a larger body of expertise, and frankly, substantial labor that needs to be put into action in order to realize the aspirations that guide the entire process.

So many thanks for this. I think the comments were terrific. Don't consider it the end of the conversation, but really a continuing conversation that will be part of the process itself. John, anything else you'd like to add?

John Halamka – Harvard Medical School – Chief Information Officer

No, great discussion and much more to come. And I codified a series of assignments, which I will write up and make sure is transmitted to the ONC. Jim?

James Walker – Geisinger Health System – CHIO

One quick thing. Is it within our scope in this meeting to recommend to ONC or whatever we would do, that we publish to the community that if there are exclusions that are onerous to people to code or execute or whatever, that those are optional? That they are not obligated to code those extensions into their systems?

John Halamka – Harvard Medical School – Chief Information Officer

So this, I guess, would be a question that would reflect back to ONC as we think about the certification process. Can an FAQ suggest what is optional and what is not? I'm not sure the community knows.

M

The intention was always, 100%, to protect reporting entities from unfairness, not to create a burden in any way at all.

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability

Again, I take that as a question that we have to discuss with ONC. But we get the point of not compromising the greater good.

James Walker – Geisinger Health System – CHIO

... a sense of this meeting today that that would be a useful thing to do? Can we do that much?

John Halamka – Harvard Medical School – Chief Information Officer

I would certainly support that, in my own experience. Is there any objection to any committee member that exclusionary criteria that are complex be declared appropriately optional, if, again, from a certification and testing perspective that has to be adjudicated. That's somewhat beyond our pay grade, but I think we can transfer that concept.

James Walker – Geisinger Health System – CHIO

Great. Thank you.

Judy Sparrow – Office of the National Coordinator – Executive Director

Okay, good, thank you. Anybody in the audience that wishes to make a public comment, please step to the microphone.

M

This is ... from ... First of all I'm very happy an indirect happened. I think it's a very good initiative. The comment I have on the HHS Website is it is nearly impossible to figure out when the next conference calls are, what number to call in to find what pass code to use, and also when the next face-to-face ... are. So if somebody could publish that and make it easy for people to find, I think you'd have more participation.

Judy Sparrow – Office of the National Coordinator – Executive Director

Okay, thank you. Anyone else in the audience? Anyone on the phone? Okay, well thank you for sticking around for the double-header.

John Halamka – Harvard Medical School – Chief Information Officer

Okay, we stand adjourned. Thank you, everybody.